MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

South African Specification for eCTD Regional - Module1

This document is intended to provide requirements to applicants wishing to submit applications for the registration of medicines in eCTD format. It reflects the current situation and will be regularly updated with change in legislation and experience gained. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

Guidelines and forms are available from the office of the Registrar of Medicines and the website.

First publication released for pilot implementation and comment	March 2013
Version 2	October 2016
Implementation	01 May 2017

DR JC GOUWS
REGISTRAR OF MEDICINES
~~**MS M HELA**~~

TABLE OF CONTENTS

LIST OF TABLES 3

ABBREVIATIONS AND ACRONYMS 4

DEFINITIONS 5

1 INTRODUCTION 6

1.1 Background 6

1.2 Scope 6

1.3 Technical Requirements 6

2 SOUTH AFRICAN REGION SPECIFIC INFORMATION: MODULE 1 7

3 SOUTH AFRICAN FILE FORMATS 7

3.1 Module 1 7

3.2 Modules 2 to 5 8

4 USE OF ELECTRONIC SIGNATURES 8

5 LINKS (PDF Hyperlinks) 8

6 HANDLING OF EMPTY OR MISSING eCTD SECTIONS 8

7 GENERAL ARCHITECTURE OF MODULE 1 8

7.1 Envelope 9

7.2 m1-za 9

7.3 Directory / File Structure 10

7.4 Node Extensions 10

7.5 File Naming Convention 10

7.6 Folder and Filename path length 10

8 CHANGE CONTROL 11

9 UPDATE HISTORY 11

Appendix 1: Directory / File Structure for ZA Module 1 12

Appendix 2: Envelope Element Description 41

Appendix 3: Example Screenshots 47

Appendix 4: Creating the XML ZA Submission 50

Appendix 5: Modularised DTD for ZA Module 1 51

LIST OF TABLES

Table 1: Overview on the content of the Module 1 12

Table 2: Directory / file structure 15

Table 3: Conventions 15

Table 4: Directory / File Structure for ZA Module 1 16

Table 5: Example of how the Related Sequence should be used 45

ABBREVIATIONS AND ACRONYMS

API	Active Pharmaceutical Ingredient
Applicant	The Proposed / Holder of Certificate of Registration
BE	Bioequivalence
BMR	Batch manufacturing record
CEP	Certificate of Suitability (Ph Eur monograph)
CoA	Certificate of Analysis
CPP	Certificate of ~~a~~ Pharmaceutical Product
CTD	Common Technical Document
DTD	Document Type Definition
eCTD	electronic Common Technical Document
EMA	European Medicines Agency
~~EU~~	~~European Union~~
EWG	Expert Working Group
GCP	Good Clinical Practice
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practice
HCR	Holder of Certificate of Registration
ICH	International ~~Conference~~ ~~on~~ Council for Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
INN	International Non-proprietary Name
IPI	Inactive Pharmaceutical Ingredient
IT	Information technology
MCC	Medicines Control Council
NCE	New Chemical Entity
OCR	Optical Character Recognition
PDF	Portable Document Format
P&A	Pharmaceutical and Analytical
PHCR	Proposed Holder of Certificate of Registration
PI	Package Insert
PIL	Patient Information Leaflet
PMF	Plasma Master File
~~UK~~	~~United Kingdom~~
~~USA~~	~~United States of America~~
VAMF	Vaccine Antigen Master File
WHO	World Health Organisation
XML	Extensible Markup Language
ZA/SA	South Africa

DEFINITIONS

Application number:	The application number is the official reference number assigned to the dossier or eCTD application by the MCC. It remains with the dossier for its full life cycle and also in archiving.
Dossier:	A collection of documents compiled by an applicant/PHCR in compliance with South African legislation and guidelines in order to seek registration of a medicine, or any amendments thereof. An application may comprise a number of submissions.
eCTD application:	A collection of electronic documents compiled by an applicant/PHCR in compliance with South African legislation and guidelines in order to seek registration of a medicine, or any amendments thereof. An eCTD application may comprise a number of eCTD Sequences. In South Africa an eCTD application may comprise several strengths, each with a unique proprietary name. Such a collection may also be described as a dossier.
eCTD identifier:	An eCTD identifier is the application number used as the directory name in the top-level directory.
eCTD Sequence:	All files and folders in a submission in eCTD format are to be placed under the eCTD-Sequence number folder (equivalent to the term "sequence" used by the EMA)
eCTD Submission:	An eCTD Submission is an electronic-only submission in the eCTD format that is supported by paper documents (e.g. some documents from Module 1).
Regulatory activity:	A regulatory activity is a logical entity of submission activity (for example a new indication) with a defined start and end point (e.g. initial submission to final approval). In the eCTD world, a regulatory activity consists of all the eCTD Sequences that together make up the lifecycle of that particular regulatory activity. It can also be defined as a collection of **sequences** covering the start to the end of a specific business process, e.g. an initial application for registration or a type C amendment. It is a concept used to group together several business related sequences.
Submission / Sequence:	A single set of information and/or documents supplied by the applicant/PHCR as a partial or complete application. In the context of eCTD, this is equivalent to 'eCTD Sequence'.
Submission Type:	The submission type describes the type of regulatory submission / type of procedure that the content relates to.

1 INTRODUCTION

This document specifies Module 1 of the electronic Common Technical Document (eCTD) for South Africa ("ZA").

eCTD is the only valid format for electronic-only submissions to the South African Regulatory Authority.

The document should be read in conjunction with the ICH eCTD Specification to prepare a valid eCTD submission for South Africa. The latest version of the ICH eCTD Specification can be found at: http://estri.ich.org/ectd.

The eCTD is defined as an interface for industry to agency transfer of regulatory information while at the same time taking into consideration the facilitation of the creation, review, life cycle management and archiving of the electronic submission.

The eCTD specification lists the criteria that will make an electronic submission technically valid. The focus of the specification is to provide the ability to transfer the registration application electronically from industry to a regulatory authority.

Industry to industry and authority to authority transfer is not addressed.

1.1 Background

The specification for the eCTD is based upon content defined within the CTD issued by the ICH M4 EWG. The CTD describes the organisation of modules, sections and documents. The structure and level of detail specified in the CTD have been used as the basis for defining the eCTD structure and content but, where appropriate, additional details have been developed within the eCTD specification.

The philosophy of the eCTD is to use open standards. Open standards, including proprietary standards which through their widespread use can be considered *de facto* standards, are deemed to be appropriate in general.

1.2 Scope

The CTD as defined by the M4 EWG does not cover the full submission that is to be made in a region. It describes only modules 2 to 5, which are common across all regions. The ICH CTD specifies that Module 1 should contain region-specific administrative and product information. The CTD does not describe the content of module 1 because it is regional specific, nor does it describe documents that can be submitted as amendments or variations to the initial application.

The value of producing a specification for the creation of an electronic submission based only upon the modules described in the CTD would be limited. Therefore, the M2 EWG has produced a specification for the eCTD that is applicable to all modules of initial registration applications and for other submissions of information throughout the life cycle of the product, such as variations and amendments.

1.3 Technical Requirements

The specification is designed to support high-level functional requirements such as the following:

- Copying and pasting
- Viewing and printing of documents
- Annotation of documentation
- Facilitating the exporting of information to databases
- Searching within and across applications
- Navigating throughout the eCTD and its subsequent amendments/variations

2 SOUTH AFRICAN REGION SPECIFIC INFORMATION: MODULE 1

The ICH Common Technical Document ("CTD") specifies that Module 1 should contain region-specific administrative and product information.

Depending on the type of application, region-specific administrative and product information has to be provided in Module 1.

Appendix 1 gives a detailed overview on all the possible documents in Module 1. Depending on the type of application, the phase of the application (e.g. initial submission, responses to recommendations) and the type of product (e.g. oral galenic form, vaccine) not all elements are to be provided. The current practice has to be taken into account. The table includes all submission types although some of them may only become suitable for eCTD submission at a later stage. Please refer to the Guidance for the submission of Regulatory Information in eCTD Format.

A Letter of Application, ~~and~~ Application Form(s) (one per strength), and a Validation Template are mandatory.

This document describes only the region-specific information that is common to all eCTD submissions in South Africa.

3 SOUTH AFRICAN FILE FORMATS

3.1 Module 1

The file formats that can be included in Module 1 are given in Table 1. PDF, as defined by the ICH eCTD Specification, is the only format acceptable – see table.

~~SA~~South African labelling and packaging documents in Module1.3, in the proprietary format MS Word should not be referenced in the eCTD backbone and should always be provided *in addition to* the PDF versions.

Note that all PDF files included in an eCTD (irrespective of the module) should be in the format PDF 1.4, 1.5, 1.6 or 1.7.

Table 1 Acceptable file formats for Module1

Document	File Format	Remark
Letter of Application	PDF	A scan of the originally signed document is mandatory. The file must be searchable (OCR scanned)
Application form	PDF	A scan of the originally signed document is mandatory. The file must be searchable (OCR scanned)
~~SA~~ZA labelling and packaging: PI, PIL and label	PDF PDF	Include working documents as MS Word (please refer to the respective section ~~chapter~~ ~~4.7~~ in the guidance document 2.23)[1] in addition to the PDF for the PI, PIL and label, for ease of review, in addition to the eCTD submission.*
Other	PDF	PDF preferably generated from electronic source.

**For the correct naming of the files please refer to the Guidance document*

In addition, the PDF files should follow the general ICH requirements of Modules 2 to 5 regarding size limitations, security settings/password protection etc. Files, folders or submissions should not be zipped.

[1] ***2.23 Guidance for the submission of regulatory information in eCTD format***

3.2 Modules 2 to 5

No additional file formats are defined for Modules 2 to 5 other than those mentioned in the ICH eCTD Specification Document.

The ICH DTD definition (and the files) remain unchanged. A detailed use of Section 3.2.R is given in the Guidance for the submission of regulatory information in eCTD format.

4 USE OF ELECTRONIC SIGNATURES

The use of advanced electronic signatures (digital signatures) will be crucial in achieving pure electronic communication between the pharmaceutical industry and regulatory agencies, particularly for authentication of electronic submissions and documents contained therein. South Africa will therefore be developing a long-term strategy to implement digital signatures. Currently however, the use of digital signatures for electronic submissions within South Africa is not fully supported and digital signatures should therefore not be used.

Scanned signatures in the electronic Module 1 are allowed since paper copies of certain documents of Module 1 including the original signed versions of the forms and the letter of application are required (please refer to the Guidance for the submission of Regulatory Information in eCTD Format for further details).

Module 1.2.2.4 should include an attestation that the paper and electronic versions of the submission, the ~~SA~~ South African labelling and packaging and the letter of application are identical.

5 LINKS (PDF Hyperlinks)

Links among objects in the eCTD submission should be relative. The intention is to make the eCTD submission self-contained.

Links among objects in Module 1 are allowed.

Hyperlinks from Module 1 to other modules are allowed.

6 HANDLING OF EMPTY OR MISSING eCTD SECTIONS

For new applications (including generic applications), detailed statements justifying the absence of data or specific eCTD sections should be provided in the relevant Quality Overall Summary and/or Non-Clinical/Clinical Overviews (Module 2.3, 2.4, 2.5). If relevant, justification for absence of data or empty sections in Module 1 is to be provided in the letter of application.

Note that placeholder documents highlighting 'no relevant content' should not be placed in the eCTD structure, as these would create a document lifecycle for non-existent documents, and unnecessary complication and maintenance of the eCTD.

7 GENERAL ARCHITECTURE OF MODULE 1

The ZA Module 1 architecture is similar to that of Modules 2 to 5 of the eCTD, comprising a directory structure and a backbone with leaves. The backbone must be a valid XML document according to the ZA Regional Document Type Definition (DTD).

The backbone (the za-regional.xml file) contains metadata for the leaves, including pointers to the files in the directory structure.

In addition, the South African Regional DTD defines metadata at the submission level in the form of an envelope. The root element is “za-backbone” and contains two elements: “za-envelope” and “m1-za”.

The ZA Regional DTD is modularised i.e. the envelope and leaves are referenced from the main part of the DTD as external entities called respectively "za-envelope.mod" and "za-leaf.mod ". The ZA "leaf" is identical to the leaf element described in the ICH eCTD DTD; refer to Table 6-8 of the ICH eCTD Specification.

A full description of the ZA Regional DTD can be found in Appendix 5 of this specification.

Examples of the directory structure for any application are given in Appendix 3 of this specification. The leaves need to be equipped with information according to the requirements for a given type of submission.

Note that files can be referenced across modules i.e. content files in Modules 2 to 5 (in the index.xml) can be referred to from the za-regional.xml (Module 1) and *vice versa*.

The eCTD contains more than documents and requires the applicant to deliver technical information such as the DTD, the MD5 checksum, additional metadata, and other information. A list of files that are required by the South African Regulatory Authority in addition to the documents is as follows:

Sequence number folder:

- index.xml: eCTD backbone file, the table of content
- index-md5.txt the MD5 checksum file

Util folder:

- dtd folder File folder for document type definition files
- style folder File folder for style sheet

DTD folder:

- za-envelope.mod
- za-leaf.mod
- za-regional.dtd ZA regional DTD
- ich-ectd-3-2.dtd ICH DTD

Style folder:

- za-regional.xsl ZA regional style sheet file
- ectd-2-0.xsl ICH style sheet file

Other file formats such as .doc may be required in addition to the PDF requirement of the eCTD. These files should not be added as leaf elements (documents) within the eCTD structure. They should be provided in a separate folder called "<eCTD sequence>-workingdocuments" (e.g. 0000-workingdocuments), on the CD/DVD containing the eCTD. Please refer to the Guidance for the submission of Regulatory Information in eCTD Format for guidance on the structure of this folder.

7.1 Envelope

The "za-envelope" element is designed to be used for all types of submissions (new products, amendments, responses, etc.) for a given medicinal product and will be required for each submission.

The envelope provides metadata at the submission level.

A description of each "envelope" element is provided in Appendix 2 of this specification.

7.2 m1-za

The "m1-za" element of the ZA regional DTD is based on the same conceptual approach as the common part of the ICH eCTD DTD. It provides an XML catalogue with metadata at the leaf level including pointers to the location of files in a directory structure. As for the ICH eCTD DTD, the "m1-za" element maps to the directory structure. (There may at times be what is seen to be a 'redundant' directory structure, but this is necessary in order to be able to use the same file / directory structure for all procedures.)

7.3 Directory / File Structure

The ZA Module 1 Specification provides the directory and file structure, see Appendix 1.

7.4 Node Extensions

Node extensions are a way of providing extra organisational information to the CTD. The node extension should be visualised as an extra heading in the CTD structure. The following rules apply to node extensions in ZA eCTDs:

- Node extensions must not be used where ICH-specified sub-headings already exist (e.g. indication, manufacturer, drug substance, drug product are all-ICH specified node extensions).
- Node extensions must only be used at the lowest level of the eCTD structure (for example a node extension can be used at the level 5.3.5.1 but must not be used at the level 5.3).
- Node extensions are mainly to be used to group together documents made up of multiple leaf elements (e.g. a clinical study made up of separate files for the synopsis, main body and individual appendices could be grouped together under a node extension with the Study Identifier as its Title attribute).
- Node extensions must be maintained over the entire life of the eCTD lifecycle (for example if a node extension is used in eCTD Sequence 0000 to group files for a study report in Module 5.3.5.1, then any files submitted in a later eCTD Sequence must also be placed under a node extension, even if only one file is submitted).
- Node extensions may be nested as this is allowed by the eCTD DTD. However, as noted in bullet 2, the first node extension must be at the lowest level in the eCTD structure (e.g. in Module 5.3. a node extension may be added to group together files with the Study Identifier as Title attribute). Further node extensions may be added as children of the Study Identifier node, separating CRFs from individual patient listings.

7.5 File Naming Convention

File names have fixed and variable components. Components are separated by a hyphen.

Fixed components are highly recommended. The variable component is optional and should be used as appropriate to further define these files. The variable component, if used, should be a meaningful concatenation of words without separation and should be kept as brief and descriptive as possible. File extensions in line with this specification should be applied as applicable.

The first component should be the fixed component of the filename, as per Appendix 1, Table 1.

The second component if necessary should be the variable component. In cases where differentiation is needed (e.g. between 1,5 mg and 15 mg), it is suggested that the word 'point' is written in full i.e. ‘1point5mg’.

There are no recommendations for variable components in this specification. The format of the file is indicated by the file extension.

File names should always be in lowercase, in line with the ICH eCTD specification. Examples are:

- application-letter-10mg.pdf
- label-10mg.pdf

7.6 Folder and Filename path length

The overall folder and filename path length starting from the sequence number should not exceed 180 characters for any file in any module.

8 CHANGE CONTROL

The ZA Module 1 specification is likely to change with time. Factors that could affect the content of the specification include, but are not limited to:

- Change in the content of the Module 1 for the CTD/eCTD, either through the amendment of information, at the same level of detail, or by provision of more detailed definition of content and structure
- Inclusion of new application types initially not included in the eCTD set
- Change to the regional requirements for applications that are outside the scope of the CTD
- Update of standards that are already in use within the eCTD
- Identification of new standards that provide additional value for the creation and/or usage of the eCTD
- Identification of new functional requirements
- Experience of use of the eCTD by all parties, in particular Module 1.

9 UPDATE HISTORY

Date	Reason for update	Version & publication
Feb 2013	First publication as working document	v1_23 working document Feb 2013
March 2013	Publication for implementation of pilot phase and comment	v1 March 2013
Sept 2016	Amendment of sections Abbreviations & Acronyms, Definitions, 2, 3.1, 4, Appendix 1, Appendix 2 (Table 5), Appendix 3, Appendix 4 Added section 7.6	v2 October 2016
1 May 2017	Implementation	

Appendix 1: Directory / File Structure for ZA Module 1

~~The following table~~ Table 1 gives an overview on the contents of Module 1. The current practice has to be taken into account to define which documents are needed according to the submission types, and the documents listed below should be provided where applicable. Please refer to the current guidelines and the Guidance for the submission of regulatory information in eCTD format to identify which documents need to be included in the submission.

File names have fixed and variable components. Components are separated by a hyphen. No hyphens or spaces should be used within individual components. The fixed components are defined in the table below. A filename is composed as follows: fixedcomponent-variablecomponent.ext (see also table 3). For each leaf described below, node extensions are allowed.

Table 1: Overview on the content of the Module 1

No	Title	Fixed Component of File Name
1.0	Letter of application	application-letter
1.2	Application	
1.2.1	Application form	application-form
1.2.2	Annexes	
1.2.2.1	Proof of payment	proof-of-payment
1.2.2.2	Letter of authorisation	letter-of-authorisation
1.2.2.3	Dossier product batch information	dossier-product-batch-information
1.2.2.4	Electronic copy declaration	electronic-copy-declaration
1.2.2.5	*Curriculum vitae* of the person responsible for pharmacovigilance	cv-pharmacovigilance
1.2.2.6	API change control	api-change-control
1.2.2.7	EMA certificate for a Vaccine Antigen Master File (VAMF)	vamf-certificate
1.2.2.8	EMA certificate for a Plasma Master File (PMF)	pmf-certificate
1.3	South African labelling and packaging	
1.3.1	South African Package Insert	
1.3.1.1	Package Insert	pi
1.3.1.2	Standard References	stdrefs
1.3.2	Patient Information Leaflet	pil
1.3.3	Labels	label
1.3.4	Braille	braille
1.4	Information about the experts	
1.4.1	Quality	quality
1.4.2	Non-clinical	non-clinical
1.4.3	Clinical	clinical

No	Title	Fixed Component of File Name
1.5	Specific requirements for different types of applications	
1.5.1	Literature based submissions	literature-based
1.5.2	Amendments/Variations	
1.5.2.1	Tabulated schedule of amendments	amendment-schedule
1.5.2.2	Medicines Register Details	medicine-register
1.5.2.3	Affidavit by Responsible Pharmacist	affidavit
1.5.3	Proprietary name applications and changes	proprietary-name
1.5.4	Genetically modified organisms	gmo
1.5.5	PI and PIL amendments/updates	pi-amendment
1.6	Environmental risk assessment	
1.6.1	Non-GMO (genetically modified organisms)	nongmo
1.6.2	GMO	gmo
1.7	Good manufacturing practice	
1.7.1	Date of last inspection of each site	last-inspection
1.7.2	Inspection reports or equivalent document	inspection-report
1.7.3	Latest GMP certificate or a copy of the appropriate licence	gmp-certificate
1.7.4	Release	
1.7.4.1	API	api
1.7.4.2	IPIs	ipi
1.7.4.3	Finished Product Release Control (FPRC) tests	fprc-tests
1.7.4.4	Finished Product Release Responsibility (FPRR) criteria	fprr-criteria
1.7.5	Confirmation of contract	contract-confirmation
1.7.6	CPP (WHO certification scheme)	cpp
1.7.7	SAPC registration	sapc-reg
1.7.8	Registration with Registrar of Companies	comp-reg
1.7.9	Other documents relating to the Applicant/PHCR	phcr
1.7.10	Sample and Documents	
1.7.10.1	Confirmation of submission of sample	confirmation-sample
1.7.10.2	Batch manufacturing record of the sample	sample-bmr
1.7.10.3	CoA of the sample	sample-coa
1.7.11	Certified copy of a permit to manufacture specified Schedule 5, Schedules 6, 7 and 8 substances	manufacturing-permit
1.7.12	Inspection flow diagram	inspection-flow-diagram
1.7.13	Organogram	organogram
1.8	Details of compliance with screening outcomes	compliance-screening
1.9	Individual patient data - statement of availability	indiv-patient-data

No	Title	Fixed Component of File Name
1.10	Foreign regulatory status	
1.10.1	List of countries in which an application for the same product as being applied for has been submitted	countries-same-appl
1.10.2	Registration certificate or marketing authorisation	foreign-reg-cert-or-ma
1.10.3	Foreign prescribing and patient information	foreign-pi
1.10.4	Data set similarities	data-set-similarities
1.11	Bioequivalence trial information	be-trial-info
1.12	Paediatric development programme	paediatric-dev-program
1.13	Risk management plan	risk-management-plan

The directory / file structure is defined in this appendix as a table containing the following information:

Table 2: Directory / file structure

Sequential number		Each item in the table has a unique sequentially assigned reference number. These reference numbers can change with each version of this appendix.
	Number	CTD section number
	Title	CTD title
	Element	Element name in the ZA Backbone
	File/Directory	File/Directory name from m1/za – should be relative path from za/m1e.g.m1-0-application-letter/application-letter.pdf. This is consistent with ICH standards. The file extension corresponds to the file type; i.e. the "pdf" extension is only illustrative.
	Comment	Comments

The following conventions are used:

Table 3: Conventions

Codes	**Definition**
FIXED	Fixed component of the filename (see table 1)
VAR *	Variable component of the filename
EXT	File extension, usually pdf
DDDD	An eCTD Sequence number made of 4 digits (e.g. 0000)

The names of the actual files and directories used should be presented in lower case in accordance with the eCTD specification. The use of upper case for those codes is for illustrative purposes only to show differentiation between the variable parts and the fixed part of the name.

*)The variable component, when used, should be a logical name and preceded by a hyphen. The variable component itself must follow the current ICH eCTD naming convention (e.g. can contain a hyphen but no spaces e.g. 10mg.pdf). When only one component is submitted in a directory, it is recommended that there is no variable component in the filename, e.g. when only the letter of application is submitted in the directory, the file name should be application-letter.pdf.

Table 4: Directory / File Structure for ZA Module 1

1	Number	1
	Title	Module 1
	Element	m1-za
	Directory	m1/za
	Comment	Top level directory for the ZA Module 1 as per ICH eCTD Specification
2	Number	1
	Title	Module 1
	Element	m1-za
	File	m1/za/za-regional.xml
	Comment	The ZA Regional XML instance including the envelope information. Note that the operation attribute for the za-regional.xml should always be set to 'new'.
3	Number	1.0
	Title	Letter of Application
	Element	m1-0-application-letter
	Directory	m1/za/10-application-letter
	Comment	
4	Number	1.0
	Title	Letter of Application
	Element	m1-0-application-letter
	File	m1/za/10-application-letter/application-letter-VAR.EXT
	Comment	

5	Number	1.2
	Title	Application
	Element	m1-2-application
	Directory	m1/za/12-application
	Comment	
6	Number	1.2.1
	Title	Application form
	Element	m1-2-1-application-form
	Directory	m1/za/12-application/121-application-form
	Comment	
7	Number	1.2.1
	Title	Application form
	Element	m1-2-1-application-form
	File	m1/za/12-application/121-application-form/application-form-VAR.EXT
	Comment	
8	Number	1.2.2
	Title	Annexes
	Element	m1-2-2-annexes
	Directory	m1/za/12-application/122-annexes
	Comment	
9	Number	1.2.2.1
	Title	Proof of payment
	Element	m1-2-2-1-proof-of-payment
	Directory	m1/za/12-application/122-annexes/1221-proof-of-payment
	Comment	

10	Number	1.2.2.1
	Title	Proof of payment
	Element	m1-2-2-1-proof-of-payment
	File	m1/za/12-application/122-annexes/1221-proof-of-payment/proof-of-payment-VAR.EXT
	Comment	
11	Number	1.2.2.2
	Title	Letter of authorisation
	Element	m1-2-2-2-letter-of-authorisation
	Directory	m1/za/12-application/122-annexes/1222-letter-of-authorisation
	Comment	Letter of authorisation for communication on behalf of the applicant/PHCR
12	Number	1.2.2.2
	Title	Letter of authorisation
	Element	m1-2-2-2-letter-of-authorisation
	File	m1/za/12-application/122-annexes/1222-letter-of-authorisation/letter-of-authorisation-VAR.EXT
	Comment	
13	Number	1.2.2.3
	Title	Dossier product batch information
	Element	m1-2-2-3-dossier-product-batch-information
	Directory	m1/za/12-application/122-annexes/1223-dossier-product-batch-information
	Comment	
14	Number	1.2.2.3
	Title	Dossier product batch information
	Element	m1-2-2-3-dossier-product-batch-information
	File	m1/za/12-application/122-annexes/1223-dossier-product-batch-information/dossier-product-batch-information-VAR.EXT
	Comment	

15	Number	1.2.2.4
	Title	Electronic copy declaration
	Element	m1-2-2-4-electronic-copy-declaration
	Directory	m1/za/12-application/122-annexes/1224-electronic-copy-declaration
	Comment	
16	Number	1.2.2.4
	Title	Electronic copy declaration
	Element	m1-2-2-4-electronic-copy-declaration
	File	m1/za/12-application/122-annexes/1224-electronic-copy-declaration/electronic-copy-declaration-VAR.EXT
	Comment	
17	Number	1.2.2.5
	Title	Curriculum vitae of the person responsible for pharmacovigilance
	Element	m1-2-2-5-cv-pharmacovigilance
	Directory	m1/za/12-application/122-annexes/1225-cv-pharmacovigilance
	Comment	
18	Number	1.2.2.5
	Title	Curriculum vitae of the person responsible for pharmacovigilance
	Element	m1-2-2-5-cv-pharmacovigilance
	File	m1/za/12-application/122-annexes/1225-cv-pharmacovigilance/cv-pharmacovigilance-VAR.EXT
	Comment	
19	Number	1.2.2.6
	Title	API change control
	Element	m1-2-2-6-api-change-control
	Directory	m1/za/12-application/122-annexes/1226-api-change-control
	Comment	

20	Number	1.2.2.6
	Title	API change control
	Element	m1-2-2-6-api-change-control
	File	m1/za/12-application/122-annexes/1226-api-change-control/api-change-control-VAR.EXT
	Comment	
21	Number	1.2.2.7
	Title	EMA certificate for a Vaccine Antigen Master File (VAMF)
	Element	m1-2-2-7-vamf-certificate
	Directory	m1/za/12-application/122-annexes/m1227-vamf-certificate
	Comment	
22	Number	1.2.2.7
	Title	EMA certificate for a Vaccine Antigen Master File (VAMF)
	Element	m1-2-2-7-vamf-certificate
	File	m1/za/12-application/122-annexes/1227-vamf-certificate/vamf-certificate-VAR.EXT
	Comment	
23	Number	1.2.2.8
	Title	EMA certificate for a Plasma Master File (PMF)
	Element	m1-2-2-8-pmf-certificate
	Directory	m1/za/12-application/122-annexes/1228-pmf-certificate
	Comment	
24	Number	1.2.2.8
	Title	EMA certificate for a Plasma Master File (PMF)
	Element	m1-2-2-8-pmf-certificate
	File	m1/za/12-application/122-annexes/1228-pmf-certificate/pmf-certificate-VAR.EXT
	Comment	

25	Number	1.3
	Title	South African labelling and packaging
	Element	m1-3-za-labelling-packaging
	Directory	m1/za/13-za-labelling-packaging
	Comment	
26	Number	1.3.1
	Title	South African Package Insert
	Element	m1-3-1-sapi
	Directory	m1/za/13-za-labelling-packaging/131-sapi
	Comment	
27	Number	1.3.1.1
	Title	Package Insert
	Element	m1-3-1-1-pi
	Directory	m1/za/13-za-labelling-packaging/131-sapi/1311-pi
	Comment	
28	Number	1.3.1.1
	Title	Package Insert
	Element	m1-3-1-1-pi
	File	m1/za/13-za-labelling-packaging/131-sapi/1311-pi/pi-VAR.EXT
	Comment	
29	Number	1.3.1.2
	Title	Standard References
	Element	m1-3-1-2-stdrefs
	Directory	m1/za/13-za-labelling-packaging/131-sapi/1312-stdrefs
	Comment	

30	Number	1.3.1.2
	Title	Standard References
	Element	m1-3-1-2-stdrefs
	File	m1/za/13-za-labelling-packaging/131-sapi/1312-stdrefs/stdrefs-VAR.EXT
	Comment	
31	Number	1.3.2
	Title	Patient Information Leaflet
	Element	m1-3-2-pil
	Directory	m1/za/13-za-labelling-packaging/132-pil
	Comment	
32	Number	1.3.2
	Title	Patient Information Leaflet
	Element	m1-3-2-pil
	File	m1/za/13-za-labelling-packaging/132-pil/pil-VAR.EXT
	Comment	
33	Number	1.3.3
	Title	Labels
	Element	m1-3-3-labels
	Directory	m1/za/13-za-labelling-packaging/133-labels
	Comment	Mock-ups and specimens of proposed South African labelling OR, if not available, a text only version of the proposed labelling
34	Number	1.3.3
	Title	Labels
	Element	m1-3-3-labels
	File	m1/za/13-za-labelling-packaging/133-labels/label-VAR.EXT
	Comment	

35	Number	1.3.4
	Title	Braille
	Element	m1-3-4-braille
	Directory	m1/za/13-za-labelling-packaging/134-braille
	Comment	For future use.
36	Number	1.3.4
	Title	Braille
	Element	m1-3-4-braille
	File	m1/za/13-za-labelling-packaging/134-braille/braille-VAR.EXT
	Comment	
37	Number	1.4
	Title	Information about the experts
	Element	m1-4-expert-information
	Directory	m1/za/14-expert-information
	Comment	
38	Number	1.4.1
	Title	Quality
	Element	m1-4-1-quality
	Directory	m1/za/14-expert-information/141-quality
	Comment	
39	Number	1.4.1
	Title	Quality
	Element	m1-4-1-quality
	File	m1/za/14-expert-information/141-quality/quality-VAR.EXT
	Comment	

40	Number	1.4.2
	Title	Non-clinical
	Element	m1-4-2-non-clinical
	Directory	m1/za/14-expert-information/142-non-clinical
	Comment	
41	Number	1.4.2
	Title	Non-clinical
	Element	m1-4-2-non-clinical
	File	m1/za/14-expert-information/142-non-clinical/non-clinical-VAR.EXT
	Comment	
42	Number	1.4.3
	Title	Clinical
	Element	m1-4-3-clinical
	Directory	m1/za/14-expert-information/143-clinical
	Comment	
43	Number	1.4.3
	Title	Clinical
	Element	m1-4-3-clinical
	File	m1/za/14-expert-information/143-clinical/clinical-VAR.EXT
	Comment	
44	Number	1.5
	Title	Specific requirements for different types of applications
	Element	m1-5-specific-requirements
	Directory	m1-za/15-specific-requirements
	Comment	

45	Number	1.5.1
	Title	Literature based submissions
	Element	m1-5-1-literature-based
	Directory	m1/za/15-specific-requirements/151-literature-based
	Comment	Methodology of literature search, including complete details of any database search strategies
46	Number	1.5.1
	Title	Literature based submissions
	Element	m1-5-1-literature-based
	File	m1/za/15-specific-requirements/151-literature-based/literature-based-VAR.EXT
	Comment	
47	Number	1.5.2
	Title	Amendments/Variations
	Element	m1-5-2-amendment
	Directory	m1/za/15-specific-requirements/152-amendment
	Comment	
48	Number	1.5.2.1
	Title	Tabulated schedule of amendments
	Element	m1-5-2-1-amendment-schedule
	Directory	m1/za/15-specific-requirements/152-amendment/1521-amendment-schedule
	Comment	
49	Number	1.5.2.1
	Title	Tabulated schedule of amendments
	Element	m1-5-2-1-amendment-schedule
	File	m1/za/15-specific-requirements/152-amendment/1521-amendment-schedule/amendment-schedule-VAR.EXT
	Comment	

50	Number	1.5.2.2
	Title	Medicines Register Details
	Element	m1-5-2-2-medicine-register
	Directory	m1/za/15-specific-requirements/152-amendment/1522-medicine-register
	Comment	
51	Number	1.5.2.2
	Title	Medicines Register Details
	Element	m1-5-2-2-medicine-register
	File	m1/za/15-specific-requirements/152-amendment/1522-medicine-register/medicine-register-VAR.EXT
	Comment	Appendix A1 of Amendments guideline and registration certificate to be included
52	Number	1.5.2.3
	Title	Affidavit by Responsible Pharmacist
	Element	m1-5-2-3-affidavit
	Directory	m1/za/15-specific-requirements/152-amendment/1523-affidavit
	Comment	
53	Number	1.5.2.3
	Title	Affidavit by Responsible Pharmacist
	Element	m1-5-2-3-affidavit
	File	m1/za/15-specific-requirements/152-amendment/1523-affidavit/affidavit-VAR.EXT
	Comment	
54	Number	1.5.3
	Title	Proprietary name applications and changes
	Element	m1-5-3-proprietary-name
	Directory	m1/za/15-specific-requirements/153-proprietary-name
	Comment	

55	Number	1.5.3
	Title	Proprietary name applications and changes
	Element	m1-5-3-proprietary-name
	File	m1/za/15-specific-requirements/153-proprietary-name/proprietary-name-VAR.EXT
	Comment	
56	Number	1.5.4
	Title	Genetically modified organisms
	Element	m1-5-4-gmo
	Directory	m1/za/15-specific-requirements/154-gmo
	Comment	
57	Number	1.5.4
	Title	Genetically modified organisms
	Element	m1-5-4-gmo
	File	m1/za/15-specific-requirements/154-gmo/gmo-VAR.EXT
	Comment	Filename
58	Number	1.5.5
	Title	PI and PIL amendments/updates
	Element	m1-5-5-pi-amendment
	Directory	m1/za/15-specific-requirements/155-pi-amendment
	Comment	
59	Number	1.5.5
	Title	PI and PIL amendments/updates
	Element	m1-5-5-pi-amendment
	File	m1/za/15-specific-requirements/155-pi-amendment/pi-amendment-VAR.EXT
	Comment	

60	Number	1.6
	Title	Environmental risk assessment
	Element	m1-6-environ-risk-assessment
	Directory	m1/za/16-environ-risk-assessment
	Comment	
61	Number	1.6.1
	Title	Non-GMO (genetically modified organisms)
	Element	m1-6-1-nongmo
	Directory	m1/za/16-environ-risk-assessment/161-nongmo
	Comment	
62	Number	1.6.1
	Title	Non-GMO (genetically modified organisms)
	Element	m1-6-1-nongmo
	File	m1/za/16-environ-risk-assessment/161-nongmo/nongmo-VAR.EXT
	Comment	
63	Number	1.6.2
	Title	GMO
	Element	m1-6-2-gmo
	Directory	m1/za/16-environ-risk-assessment/162-gmo
	Comment	
64	Number	1.6.2
	Title	GMO
	Element	m1-6-2-gmo
	File	m1/za/16-environ-risk-assessment/162-gmo/gmo-VAR.EXT
	Comment	

65	Number	1.7
	Title	Good manufacturing practice
	Element	m1-7-gmp
	Directory	m1/za/17-gmp
	Comment	
66	Number	1.7.1
	Title	Date of last inspection of each site
	Element	m1-7-1-last-inspection
	Directory	m1/za/17gmp/171-last-inspection
	Comment	
67	Number	1.7.1
	Title	Date of last inspection of each site
	Element	m1-7-1-last-inspection
	File	m1/za/17-gmp/171-last-inspection/last-inspection-VAR.EXT
	Comment	
68	Number	1.7.2
	Title	Inspection reports or equivalent document
	Element	m1-7-2-inspection-report-or-equivalent
	Directory	m1/za/17-gmp/172-inspection-report-or-equivalent
	Comment	
69	Number	1.7.2
	Title	Inspection reports or equivalent document
	Element	m1-7-2-inspection-report-or-equivalent
	File	m1/za/17-gmp/172-inspection-report-or-equivalent/inspection-report-VAR.EXT
	Comment	

70	Number	1.7.3
	Title	Latest GMP certificate or a copy of the appropriate licence
	Element	m1-7-3-gmp-certificate
	Directory	m1/za/17-gmp/173-gmp-certificate
	Comment	
71	Number	1.7.3
	Title	Latest GMP certificate or a copy of the appropriate licence
	Element	m1-7-3-gmp-certificate
	File	m1/za/17-gmp/173-gmp-certificate/gmp-certificate-VAR.EXT
	Comment	
72	Number	1.7.4
	Title	Release
	Element	m1-7-4-release
	Directory	m1/za/17-gmp/174-release
	Comment	General place holder for specific requirements information
73	Number	1.7.4.1
	Title	API
	Element	m1-7-4-1-api
	Directory	m1/za/17-gmp/174-release/1741-api
	Comment	
74	Number	1.7.4.1
	Title	API
	Element	m1-7-4-1-api
	File	m1/za/17-gmp/174-release/1741-api/api-VAR.EXT
	Comment	Identification and assay of the API will be performed irrespective of the possession of a CoA from the manufacturer

75	Number	1.7.4.2
	Title	IPIs
	Element	m1-7-4-2-ipi
	Directory	m1/za/17-gmp/174-release/1742-ipi
	Comment	
76	Number	1.7.4.2
	Title	IPIs
	Element	m1-7-4-2-ipi
	File	m1/za/17-gmp/174-release/1742-ipi/ipi-VAR.EXT
	Comment	Identification of the IPI will be performed irrespective of the possession of a CoA from the manufacturer
77	Number	1.7.4.3
	Title	Finished Product Release Control (FPRC) tests
	Element	m1-7-4-3-fprc-tests
	Directory	m1/za/17-gmp/174-release/1743-fprc-tests
	Comment	
78	Number	1.7.4.3
	Title	Finished Product Release Control (FPRC) tests
	Element	m1-7-4-3-fprc-tests
	File	m1/za/17-gmp/174-release/1743-fprc-tests/fprc-tests-VAR.EXT
	Comment	For imported products at least the identification and assay of the API content should be performed by an approved laboratory (FPRC) after importation.
79	Number	1.7.4.4
	Title	Finished Product Release Responsibility (FPRR) criteria
	Element	m1-7-4-4-fprr-criteria
	Directory	m1/za/17-gmp/174-release/1744-fprr-criteria
	Comment	

80	Number	1.7.4.4
	Title	Finished Product Release Responsibility (FPRR) criteria
	Element	m1-7-4-4-fprr-criteria
	File	m1/za/17-gmp/174-release/1744-fprr-criteria/fprr-criteria-VAR.EXT
	Comment	
81	Number	1.7.5
	Title	Confirmation of contract
	Element	m1-7-5-contract-confirmation
	Directory	m1/za/17-gmp/175-contract-confirmation
	Comment	Confirmation of technical contract between manufacturer/s, packer/s, FPRC/s and HCR/PHCR
82	Number	1.7.5
	Title	Confirmation of contract
	Element	m1-7-5-contract-confirmation
	File	m1/za/17-gmp/175-contract-confirmation/contract-confirmation-VAR.EXT
	Comment	
83	Number	1.7.6
	Title	CPP (WHO certification scheme)
	Element	m1-7-6-cpp
	Directory	m1/za/17-gmp/176-cpp
	Comment	
84	Number	1.7.6
	Title	CPP (WHO certification scheme)
	Element	m1-7-6-cpp
	File	m1/za/17-gmp/176-cpp/cpp-VAR.EXT
	Comment	

85	Number	1.7.7
	Title	SAPC registration
	Element	m1-7-7-sapc-reg
	Directory	m1/za/17-gmp/177-sapc-reg
	Comment	
86	Number	1.7.7
	Title	SAPC registration
	Element	m1-7-7-sapc-reg
	File	m1/za/17-gmp/177-sapc-reg/sapc-reg-VAR.EXT
	Comment	Proof of current registration of the Responsible Pharmacist by the SAPC in terms of Act 53 (Pharmacy Act), proof of current registration of the pharmacist signing the dossier by the SAPC in terms of Act 53 (Pharmacy Act) (if different from the Responsible Pharmacist), proof of registration of the Applicant/PHCR as a pharmacy or a pharmacist (read with guidelines)
87	Number	1.7.8
	Title	Registration with Registrar of Companies
	Element	m1-7-8-comp-reg
	Directory	m1/za/17-gmp/178-comp-reg
	Comment	
88	Number	1.7.8
	Title	Registration with Registrar of Companies
	Element	m1-7-8-comp-reg
	File	m1/za/17-gmp/178-comp-reg/comp-reg-VAR.EXT
	Comment	A copy of the certificate of registration of the company with the Registrar of Companies (if relevant)
89	Number	1.7.9
	Title	Other documents relating to the Applicant/PHCR
	Element	m1-7-9-docs-phcr
	Directory	m1/za/1-gmp/179-docs-phcr
	Comment	

90	Number	1.7.9
	Title	Other documents relating to the Applicant/PHCR
	Element	m1-7-9-docs-phcr
	File	m1/za/17-gmp/179-docs-phcr/phcr-VAR.EXT
	Comment	Letters of cession and acceptance, old and new company letterheads where applicable
91	Number	1.7.10
	Title	Sample and Documents
	Element	m1-7-10-sample-documents
	Directory	m1/za/17-gmp/1710-sample-documents
	Comment	
92	Number	1.7.10.1
	Title	Confirmation of submission of sample
	Element	m1-7-10-1-sample-submission-confirmation
	Directory	m1/za/17-gmp/1710-sample-documents/17101-sample-submission-confirmation
	Comment	
93	Number	1.7.10.1
	Title	Confirmation of submission of sample
	Element	m1-7-10-1-sample-submission-confirmation
	File	m1/za/17-gmp/1710-sample-documents/17101-sample-submission-confirmation/confirmation-sample-VAR.EXT
	Comment	
94	Number	1.7.10.2
	Title	Batch manufacturing record of the sample
	Element	m1-7-10-2-sample-bmr
	Directory	m1/za/17-gmp/1710-sample-documents/17102-sample-bmr
	Comment	Include information as per module 1 a) Confirmation of inclusion of batch manufacturing record in Module 3.2.R.7 or b) Batch manufacturing record of the sample available for inspection

95	Number	1.7.10.2
	Title	Batch manufacturing record of the sample
	Element	m1-7-10-2-sample-bmr
	File	m1/za/17-gmp/1710-sample-documents/17102-sample-bmr/sample-bmr-VAR.EXT
	Comment	
96	Number	1.7.10.3
	Title	CoA of the sample
	Element	m1-7-10-3-sample-coa
	Directory	m1/za/17-gmp/1710-sample-documents/17103-sample-coa
	Comment	
97	Number	1.7.10.3
	Title	CoA of the sample
	Element	m1-7-10-3-sample-coa
	File	m1/za/17-gmp/1710-sample-documents/17103-sample-coa/sample-coa-VAR.EXT
	Comment	
98	Number	1.7.11
	Title	Certified copy of a permit to manufacture specified Schedule 5, Schedules 6, 7 and 8 substances
	Element	m1-7-11-manufacturing-permit
	Directory	m1/za/17-gmp/1711-manufacturing-permit
	Comment	
99	Number	1.7.11
	Title	Certified copy of a permit to manufacture specified Schedule 5, Schedules 6, 7 and 8 substances
	Element	m1-7-11-manufacturing-permit
	File	m1/za/17-gmp/1711-manufacturing-permit/manufacturing-permit-VAR.EXT
	Comment	

100	Number	1.7.12
	Title	Inspection flow diagram
	Element	m1-7-12-inspection-flow-diagram
	Directory	m1/za/17-gmp/1712-inspection-flow-diagram
	Comment	
101	Number	1.7.12
	Title	Inspection flow diagram
	Element	m1-7-12-inspection-flow-diagram
	File	m1/za/17-gmp/1712-inspection-flow-diagram/inspection-flow-diagram-VAR.EXT
	Comment	
102	Number	1.7.13
	Title	Organogram
	Element	m1-7-13-organogram
	Directory	m1/za/17-gmp/1713-organogram
	Comment	
103	Number	1.7.13
	Title	Organogram
	Element	m1-7-13-organogram
	File	m1/za/17-gmp/1713-organogram/organogram-VAR.EXT
	Comment	
104	Number	1.8
	Title	Details of compliance with screening outcomes
	Element	m1-8-compliance-screening
	Directory	m1/za/18-compliance-screening
	Comment	

105	Number	1.8
	Title	Details of compliance with screening outcomes
	Element	m1-8-compliance-screening
	File	m1/za/18-compliance-screening/compliance-screening-VAR.EXT
	Comment	
106	Number	1.9
	Title	Individual patient data - statement of availability
	Element	m1-9-indiv-patient-data
	Directory	m1/za/19-indiv-patient-data
	Comment	
107	Number	1.9
	Title	Individual patient data - statement of availability
	Element	m1-9-indiv-patient-data
	File	m1/za/19-indiv-patient-data/indiv-patient-data-VAR.EXT
	Comment	
108	Number	1.10
	Title	Foreign regulatory status
	Element	m1-10-foreign-reg-status
	Directory	m1/za/110-foreign-reg-status
	Comment	
109	Number	1.10.1
	Title	List of countries in which an application for the same product as being applied for has been submitted
	Element	m1-10-1-countries-same-appl
	Directory	m1/za/110-foreign-reg-status/1101-countries-same-appl
	Comment	

110	Number	1.10.1
	Title	List of countries in which an application for the same product as being applied for has been submitted
	Element	m1-10-1-countries-same-appl
	File	m1/za/110-foreign-reg-status/1101-countries-same-appl/countries-same-appl-VAR.EXT
	Comment	
111	Number	1.10.2
	Title	Registration certificate or marketing authorisation
	Element	m1-10-2-foreign-reg-certif-or-ma
	Directory	m1/za/110-foreign-reg-status/1102-foreign-reg-certif-or-ma
	Comment	
112	Number	1.10.2
	Title	Registration certificate or marketing authorisation
	Element	m1-10-2-foreign-reg-certif-or-ma
	File	m1/za/110-foreign-reg-status/1102-foreign-reg-certif-or-ma/foreign-reg-cert-or-ma-VAR.EXT
	Comment	
113	Number	1.10.3
	Title	Foreign prescribing and patient information
	Element	m1-10-3-foreign-pi
	Directory	m1/za/110-foreign-reg-status/1103-foreign-pi
	Comment	
114	Number	1.10.3
	Title	Foreign prescribing and patient information
	Element	m1-10-3-foreign-pi
	File	m1/za/110-foreign-reg-status/1103-foreign-pi/foreign-pi-VAR.EXT
	Comment	

115	Number	1.10.4
	Title	Data set similarities
	Element	m1-10-4-data-set-similarities
	Directory	m1/za/110-foreign-reg-status/1104-data-set-similarities
	Comment	
116	Number	1.10.4
	Title	Data set similarities
	Element	m1-10-4-data-set-similarities
	File	m1/za/110-foreign-reg-status/1104-data-set-similarities/data-set-similarities-VAR.EXT
	Comment	
117	Number	1.11
	Title	Bioequivalence trial information
	Element	m1-11-be-trial-info
	Directory	m1/za/111-be-trial-info
	Comment	
118	Number	1.11
	Title	Bioequivalence trial information
	Element	m1-11-be-trial-info
	File	m1/za/111-be-trial-info/be-trial-info-VAR.EXT
	Comment	
119	Number	1.12
	Title	Paediatric development programme
	Element	m1-12-paediatric-dev-program
	Directory	m1/za/112-paediatric-dev-program
	Comment	For future use

120	Number	1.12
	Title	Paediatric development programme
	Element	m1-12-paediatric-dev-program
	File	m1/za/112-paediatric-dev-program/paediatric-dev-program-VAR.EXT
	Comment	
121	Number	1.13
	Title	Risk management plan
	Element	m1-13-risk-management-plan
	Directory	m1/za/113-risk-management-plan
	Comment	
122	Number	1.13
	Title	Risk management plan
	Element	m1-13-risk-management-plan
	File	m1/za/113-risk-management-plan/risk-management-plan-VAR.EXT
	Comment	

Appendix 2: Envelope Element Description

The “za-envelope” element is the root element that defines metadata of the submission. This element may contain several envelope entries.

Element	Attribute	Description/Instructions	Constraint	Occurrence
za-envelope		Root element that provides metadata for the submission.	Mandatory	Unique
application-number		This is the number issued for the product by the MCC and remains for the full lifecycle of the product from the first data submission.	Mandatory	Repeatable
applicant		The name of the applicant/HCR submitting the eCTD.	Mandatory	Unique
proprietary-name		The name of the medicinal product. Include even if not yet approved.	Mandatory	Repeatable
dosage-form		The dosage form of the medicinal product.	Mandatory	Repeatable
inn		The INN of the API(s) accompanied by its salt or hydrate form (if relevant) or chemical description of the API(s).	Mandatory	Repeatable
ectd-sequence number		This is the sequence number of the data submission –this should start at 0000 for the initial data submission lodged as an eCTD, and then increase incrementally with each subsequent data submission related to the same product e.g. 0000, 0001, 0002, 0003.	Mandatory	Unique
related-ectd-sequence number		This is the sequence number of a previous submission to which this submission relates (e.g. Response to pre-reg recommendation).	Optional	Repeatable

Element	Attribute	Description/Instructions	Constraint	Occurrence
Submission		Provides administrative information associated with the submission.	Mandatory	Repeatable ~~Unique~~
	type	The type of regulatory submission that this data submission relates to. The following are the valid values: ▪ New application, including: • **na-nce-ph**: New Chemical Entity – Pharmaceutical • **na-nce-b**: New Chemical Entity – Biological • **na-ms**: Multisource • **na-bs**: Biosimilar • **na-le**: Line extension • **na-cu**: Call-up • **na-cam~~s~~**: Complementary ~~and Alternative~~ Medicines ▪ Response to pre-reg recommendation: • **pre-reg-pa**: Pharmaceutical and ~~&~~ Analytical • **pre-reg-cl**: Clinical • **pre-reg-pn**: Proprietary name • **pre-reg-sch:** Scheduling • **pre-reg-insp:** Inspectorate • ~~**pre-reg-pa-insp:** Pharmaceutical & Analytical and Inspectorate~~ • **pre-reg-biol:** Biological committee response • **pre-reg-cam~~s~~:** Complementary ~~and Alternative~~ Medicines • **pre-reg-cr:** Response to Council resolutions	Mandatory	Unique

Element	Attribute	Description/Instructions	Constraint	Occurrence
		▪ Post-registration: • **post-reg-insp**: Inspectorate • **post-reg-pa**: Pharmaceutical and ~~&~~ Analytical • ~~**post-reg-pa-insp**: Pharmaceutical & Analytical and Inspectorate~~ • **post-reg-cl**: Clinical • **post-reg-pn:** Proprietary name change application • **post-reg-pn-update:** Updates following a proprietary name change approval • **post-reg-hcr:** Applicant transfer, name and address change of applicant • **post-reg-biol**: Biologicals and biosimilars • **post-reg-c~~a~~ams~~**: Complementary ~~and Alternative~~ Medicines ▪ Response to post-registration recommendation: • **resp-post-reg-insp:** Inspectorate • **resp-post-reg-pa:** Pharmaceutical and Analytical • **resp-post-reg-cl:** Clinical • **resp-post-reg-pn:** Proprietary name change application • **resp-post-reg-pn-update:** Updates following a proprietary name change approval • **resp-post-reg-hcr:** Applicant transfer, name and address change of applicant • **resp-post-reg-biol:** Biologicals and biosimilars • **resp-post-reg-cm:** Complementary Medicines		

Element	Attribute	Description/Instructions	Constraint	Occurrence
		▪ Withdrawal / cancellation • **withdrawal**: Withdrawal of a submission • **cancellation**: Cancellation of a registered product ▪ Baseline submissions • **baseline**: Reformatting from Paper to eCTD		
submission/efficacy		Proof of efficacy	Mandatory	Repeatable
	data-type	The data type submitted as proof of efficacy • **non-cl**: Non-clinical • **cl**: Clinical • **be**: Bioequivalence study • **other**: Other • **na**: Not applicable	Mandatory	Unique
	description	A description should be provided if the data type is set to <other>	Optional	Unique
multiple / duplicate applications			Optional	Repeatable
	proprietary-names	The name of the multiple / duplicate applications of the medicinal product. Include even if the name not yet approved.	Mandatory	Unique
	~~date-of-applications~~ application-numbers	The ~~date of~~ application number/s of the duplicate applications.	Mandatory	Unique

Example of the use of the Related Sequence

The related sequence number describes the relationship of additional information to the original submission or subsequent submissions.

An illustration of how the related sequence number is used to describe the relationship of additional information to the original and subsequent submissions follows.

Table 5: Example of how the Related Sequence should be used

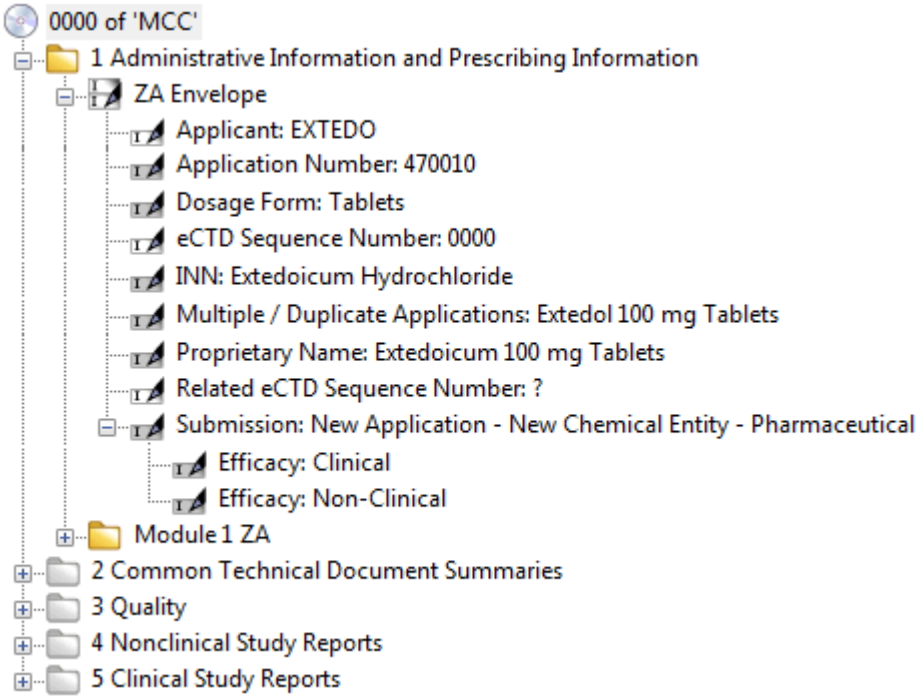
Sequence	Submission Type	Submission Description	Related eCTD Sequence	Submission Type Related Sequence	Comment
0000	na-nce-ph	New medicine application for a NCE pharmaceutical	<none>	<none>	This sequence is a new regulatory activity (New medicine application) and so no related sequence is included
0001	pre-reg-pn	Response to Proprietary Name recommendation for the NCE	0000	na-nce-ph	This is a continuation of the regulatory activity initiated in 0000 and so the related eCTD sequence points to the beginning of that regulatory activity
0002	pre-reg-pa	Response to P&A recommendation for the NCE	0000	na-nce-ph	This is a continuation of the regulatory activity initiated in 0000 and so the related eCTD sequence points to the beginning of that regulatory activity
0003	pre-reg-cl	Response to Clinical recommendation for the NCE	0000 0002	na-nce-ph pre-reg-pa	This is a continuation of the regulatory activity initiated in 0000 and includes P&A labelling recommendations and so the related eCTD sequence points to the beginning of that regulatory activity as well as the P&A response
0004	pre-reg-pa	Response to second P&A recommendation for the NCE	0000 0001 0002	na-nce-ph pre-reg-pn pre-reg-pa	This is a continuation of the regulatory activity initiated in 0000 and 0002 and includes the approved amended proprietary name, and so the related eCTD sequence points to the beginning of that regulatory activity, the first P&A response, as well as the Proprietary Name response

Sequence	Submission Type	Submission Description	Related eCTD Sequence	Submission Type Related Sequence	Comment
0005	pre-reg-cl	Response to second Clinical recommendation for the NCE	0000 0001 0003 0004	na-nce-ph pre-reg-pn pre-reg-cl pre-reg-pa	This is a continuation of the regulatory activity initiated in 0000 and 0003 and includes the approved amended proprietary name, and includes P&A labelling recommendations, so the related eCTD sequence points to the beginning of that activity, the first Clinical response, second P&A response, as well as the Proprietary Name response
0006	post-reg-pa	Application for shelf-life extension of the NCE	<none>	<none>	This is a new regulatory activity and so no related eCTD sequence is included
0007	post-reg-cl	Application for a new indication for the NCE	<none>	<none>	This is a new regulatory activity and so no related eCTD sequence is included
0008	post-reg-pa	Application for an additional API manufacturer for the NCE	<none>	<none>	This is a new regulatory activity and so no related eCTD sequence is included
0009	resp-post-reg-pa	Response to P&A recommendation on the shelf-life extension for the NCE	0006	post-reg-pa	This is a continuation of the regulatory activity initiated in 0006 and so the related eCTD sequence points to the beginning of that activity
0010	resp-post-reg-pa	Response to P&A recommendation on the additional API manufacturer for the NCE	0008	post-reg-pa	This is a continuation of the regulatory activity initiated in 0008and so the related eCTD sequence points to the beginning of that activity
0011	resp-post-reg-cl	Response to Clinical recommendation on the new indication for the NCE	0007	post-reg-cl	This is a continuation of the regulatory activity initiated in 0007 and so the related eCTD sequence points to the beginning of that activity

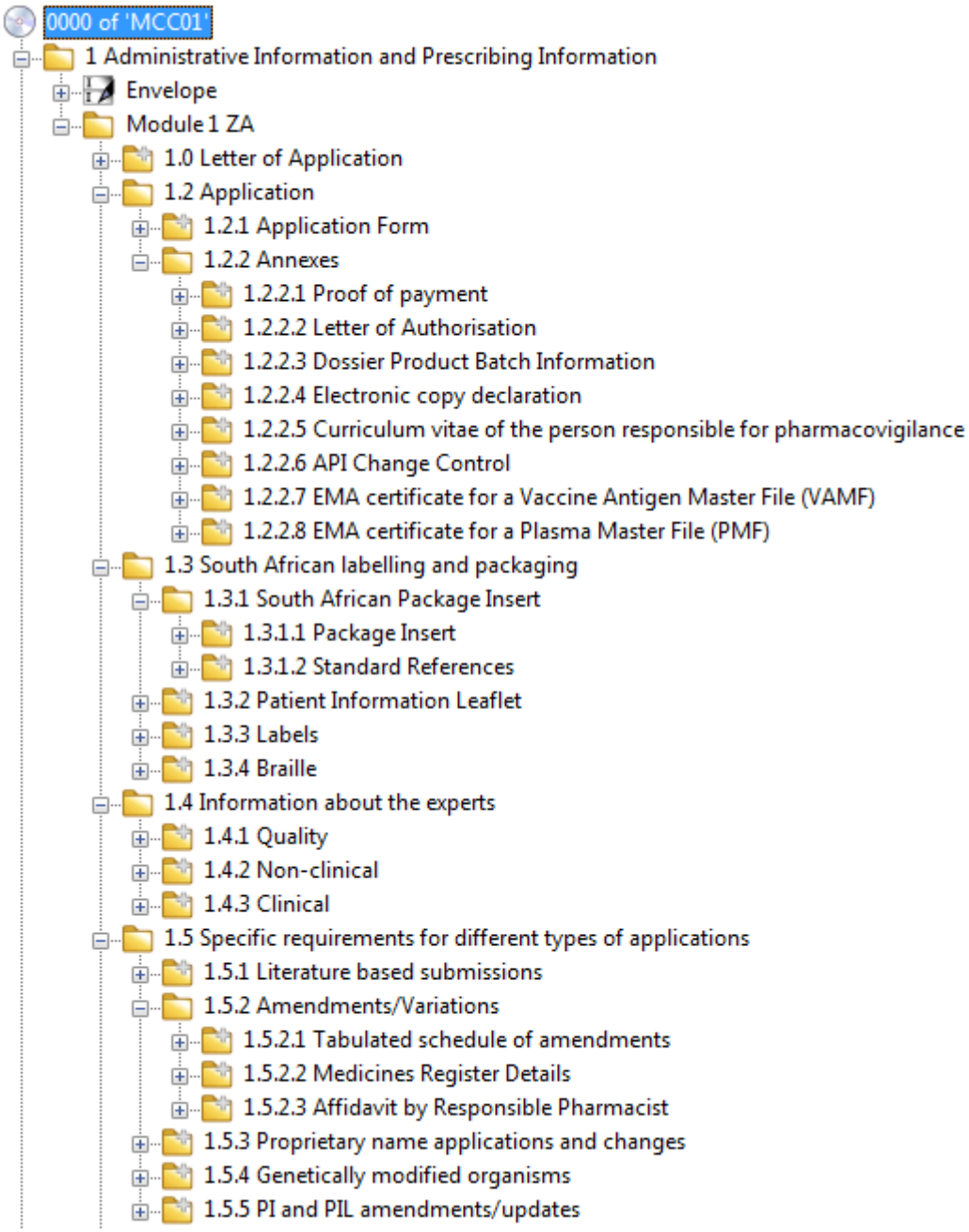
Appendix 3: Example Screenshots

This appendix is included to demonstrate how the envelope and directory structure may appear.

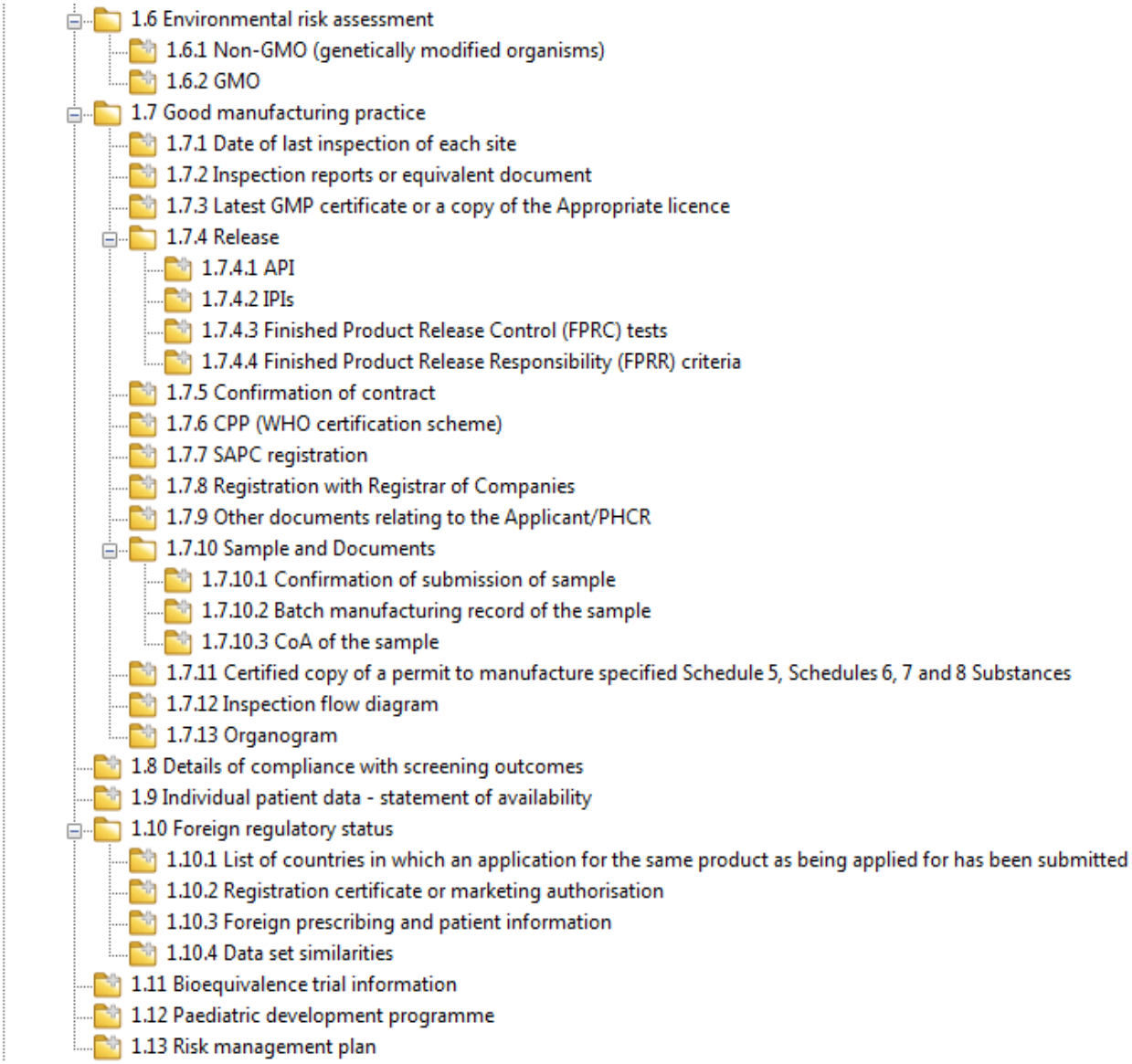
Structure of the Envelope replaced



Directory Structure – Part 1



Directory Structure – Part 2



Appendix 4: Creating the XML ZA Submission

Details of the name used for the root directory (eCTD identifier) should always be included in the letter of application. The new application and subsequent submissions should use the same top-level directory name. Each submission should be differentiated by a sub-directory named according to the eCTD Sequence number of the submission to the authority. The application number and eCTD Sequence number should be included in the "za-envelope" element of the ZA Regional instance. The first sub-directory below the top-level directory for the original submission should have the eCTD Sequence number "0000" and e.g. the three subsequent submissions respectively "0001", "0002" and "0003".

See 2.23 Guidance for the submission of regulatory information in eCTD format, relevant section ~~chapter~~, ~~3.1.1~~ for further information on the eCTD identifier.

Appendix 5: Modularised DTD for ZA Module 1

za-regional.dtd:

```
<!--
MCC ZA Regional DTD M1
Version: 2.0
State: final
Date: 02/09/2016
Authors: EXTEDO
Reference: ZA Ectd Module 1 Technical Specification V2.0


Meaning of the suffixes:
  ?      : element is optional; must appear 0 or 1 time
  *      : element is optional; must appear 0 or more times
  +      : element is mandatory; must appear 1 or more times
  <none> : element is mandatory; must appear once and only once
-->

<!ENTITY % leaf-node "(( leaf | node-extension )*)">
<!ENTITY % envelope-module SYSTEM "za-envelope.mod">
%envelope-module;
<!ENTITY % leaf-module SYSTEM "za-leaf.mod">
%leaf-module;


<!-- Root element za-backbone -->
<!ELEMENT mcc:za-backbone (
          za-envelope,
          m1-za
)>
<!ATTLIST mcc:za-backbone
  xmlns:mcc      CDATA #FIXED "http://www.mccza.com"
  xmlns:xlink    CDATA #FIXED "http://www.w3c.org/1999/xlink"
  dtd-version    CDATA #FIXED "2.0"
  xml:lang       CDATA #IMPLIED
>

<!-- ..................................................................... -->
<!ELEMENT m1-za (
        m1-0-application-letter,
                  m1-2-application?,
        m1-3-za-labelling-packaging?,
        m1-4-expert-information?,
        m1-5-specific-requirements?,
        m1-6-environ-risk-assessment?,
        m1-7-gmp?,
        m1-8-compliance-screening?,
        m1-9-indiv-patient-data?,
        m1-10-foreign-reg-status?,
        m1-11-be-trial-info?,
        m1-12-paediatric-dev-program?,
        m1-13-risk-management-plan?
)>
<!-- ..................................................................... -->
<!ELEMENT m1-0-application-letter (%leaf-node;)>
```

```
<!-- ..... -->
<!ELEMENT m1-2-application (
        m1-2-1-application-form?,
        m1-2-2-annexes?
)>
<!-- ..... -->
<!ELEMENT m1-2-1-application-form (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-2-2-annexes (
        m1-2-2-1-proof-of-payment?,
        m1-2-2-2-letter-of-authorisation?,
        m1-2-2-3-dossier-product-batch-information?,
        m1-2-2-4-electronic-copy-declaration?,
        m1-2-2-5-cv-pharmacovigilance?,
        m1-2-2-6-api-change-control?,
        m1-2-2-7-vamf-certificate?,
        m1-2-2-8-pmf-certificate?
)>
<!-- ..... -->
<!ELEMENT m1-2-2-1-proof-of-payment (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-2-2-2-letter-of-authorisation (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-2-2-3-dossier-product-batch-information (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-2-2-4-electronic-copy-declaration (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-2-2-5-cv-pharmacovigilance (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-2-2-6-api-change-control (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-2-2-7-vamf-certificate (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-2-2-8-pmf-certificate (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-3-za-labelling-packaging (
        m1-3-1-sapi?,
        m1-3-2-pil?,
        m1-3-3-labels?,
        m1-3-4-braille?
)>
<!-- ..... -->
<!ELEMENT m1-3-1-sapi (
        m1-3-1-1-pi?,
        m1-3-1-2-stdrefs?
)>
<!ELEMENT m1-3-1-1-pi (%leaf-node;)>
<!ELEMENT m1-3-1-2-stdrefs (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-3-2-pil (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-3-3-labels (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-3-4-braille (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-4-expert-information (
        m1-4-1-quality?,
        m1-4-2-non-clinical?,
        m1-4-3-clinical?
```

```
)>
<!ELEMENT m1-4-1-quality (%leaf-node;)>
<!ELEMENT m1-4-2-non-clinical (%leaf-node;)>
<!ELEMENT m1-4-3-clinical (%leaf-node;)>

<!-- ..... -->
<!ELEMENT m1-5-specific-requirements (
        m1-5-1-literature-based?,
        m1-5-2-amendment?,
        m1-5-3-proprietary-name?,
        m1-5-4-gmo?,
        m1-5-5-pi-amendment?
)>
<!-- ..... -->
<!ELEMENT m1-5-1-literature-based (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-5-2-amendment (
        m1-5-2-1-amendment-schedule?,
        m1-5-2-2-medicine-register?,
        m1-5-2-3-affidavit?
)>
<!ELEMENT m1-5-2-1-amendment-schedule (%leaf-node;)>
<!ELEMENT m1-5-2-2-medicine-register (%leaf-node;)>
<!ELEMENT m1-5-2-3-affidavit (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-5-3-proprietary-name (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-5-4-gmo (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-5-5-pi-amendment (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-6-environ-risk-assessment (
        m1-6-1-nongmo?,
        m1-6-2-gmo?
)>
<!ELEMENT m1-6-1-nongmo (%leaf-node;)>
<!ELEMENT m1-6-2-gmo (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-7-gmp (
        m1-7-1-last-inspection?,
        m1-7-2-inspection-report-or-equivalent?,
        m1-7-3-gmp-certificate?,
        m1-7-4-release?,
        m1-7-5-contract-confirmation?,
        m1-7-6-cpp?,
        m1-7-7-sapc-reg?,
        m1-7-8-comp-reg?,
        m1-7-9-docs-phcr?,
        m1-7-10-sample-documents?,
        m1-7-11-manufacturing-permit?,
        m1-7-12-inspection-flow-diagram?,
        m1-7-13-organogram?
)>
<!-- ..... -->
<!ELEMENT m1-7-1-last-inspection (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-7-2-inspection-report-or-equivalent (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-7-3-gmp-certificate (%leaf-node;)>
```

```
<!-- ..... -->
<!ELEMENT m1-7-4-release (
        m1-7-4-1-api?,
        m1-7-4-2-ipi?,
        m1-7-4-3-fprc-tests?,
        m1-7-4-4-fprr-criteria?
)>
<!ELEMENT m1-7-4-1-api (%leaf-node;)>
<!ELEMENT m1-7-4-2-ipi (%leaf-node;)>
<!ELEMENT m1-7-4-3-fprc-tests (%leaf-node;)>
<!ELEMENT m1-7-4-4-fprr-criteria (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-7-5-contract-confirmation (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-7-6-cpp (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-7-7-sapc-reg (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-7-8-comp-reg (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-7-9-docs-phcr (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-7-10-sample-documents (
        m1-7-10-1-sample-submission-confirmation?,
        m1-7-10-2-sample-bmr?,
        m1-7-10-3-sample-coa?
)>
<!ELEMENT m1-7-10-1-sample-submission-confirmation (%leaf-node;)>
<!ELEMENT m1-7-10-2-sample-bmr (%leaf-node;)>
<!ELEMENT m1-7-10-3-sample-coa (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-7-11-manufacturing-permit (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-7-12-inspection-flow-diagram (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-7-13-organogram (%leaf-node;)>

<!-- ..... -->
<!ELEMENT m1-8-compliance-screening (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-9-indiv-patient-data (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-10-foreign-reg-status (
        m1-10-1-countries-same-appl?,
        m1-10-2-foreign-reg-certif-or-ma?,
        m1-10-3-foreign-pi?,
        m1-10-4-data-set-similarities?
)>
<!-- ..... -->
<!ELEMENT m1-10-1-countries-same-appl (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-10-2-foreign-reg-certif-or-ma (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-10-3-foreign-pi (%leaf-node;)>
<!-- ..... -->
<!ELEMENT m1-10-4-data-set-similarities (%leaf-node;)>

<!-- ..... -->
<!ELEMENT m1-11-be-trial-info (%leaf-node;)>
```

```
<!-- ..................................................................... -->
<!ELEMENT m1-12-paediatric-dev-program (%leaf-node;)>
<!-- ..................................................................... -->
<!ELEMENT m1-13-risk-management-plan (%leaf-node;)>
```

za-envelope.mod:

```
<!--
MCC ZA Regional Envelope MOD
Version: 2.0
State: final
Date: 08/09/2016
Authors: EXTEDO

Meaning of the suffixes:
  ?      : element is optional; must appear 0 or 1 time
  *      : element is optional; must appear 0 or more times
  +      : element is mandatory; must appear 1 or more times
  <none>         : element is mandatory; must appear once and only once
-->

<!-- ..................................................................... -->
<!ELEMENT za-envelope (
  application-number+,
  applicant,
  proprietary-name+,
  dosage-form+,
  inn+,
  ectd-sequence,
  related-ectd-sequence*,
  submission+,
  multiple-applications*
)>

<!-- ..................................................................... -->
<!ELEMENT application-number (#PCDATA)>
<!ELEMENT applicant (#PCDATA)>
<!ELEMENT proprietary-name (#PCDATA)>
<!ELEMENT dosage-form (#PCDATA)>
<!ELEMENT inn (#PCDATA)>
<!ELEMENT ectd-sequence (#PCDATA)>
<!ELEMENT related-ectd-sequence (#PCDATA)>
<!ELEMENT submission (efficacy+)>
<!ATTLIST submission
  type    (na-nce-ph
                    |na-nce-b
                    |na-ms
                    |na-bs
                    |na-le
                    |na-cu
                    |na-cm
                    |pre-reg-pa
                    |pre-reg-cl
                    |pre-reg-pn
                    |pre-reg-sch
                    |pre-reg-insp
                    |pre-reg-biol
                    |pre-reg-cm
                    |pre-reg-cr
                    |post-reg-insp
                    |post-reg-pa
                    |post-reg-cl
                    |post-reg-pn
```

```
                |post-reg-pn-update
                |post-reg-hcr
                |post-reg-biol
                |post-reg-cm
                |resp-post-reg-insp
                |resp-post-reg-pa
                |resp-post-reg-cl
                |resp-post-reg-pn
                |resp-post-reg-pn-update
                |resp-post-reg-hcr
                |resp-post-reg-biol
                |resp-post-reg-cm
                |withdrawal
                |cancellation
                |baseline) #REQUIRED
>
<!ELEMENT multiple-applications EMPTY>
<!ATTLIST multiple-applications
  proprietary-names CDATA #REQUIRED
  date-of-applications CDATA #REQUIRED
>
<!ELEMENT efficacy EMPTY>
<!ATTLIST efficacy
        data-type       (non-cl
                                |cl
                                |be
                                |other
                                |na) #REQUIRED
        description CDATA #IMPLIED
>
```

za-leaf.mod:

```
<!--
MCC ZA Regional Leaf MOD
Version: 2.0
State: final
Date: 02/09/2016
Authors: EXTEDO

Meaning of the suffixes:
  ?          : element is optional; must appear 0 or 1 time
  *          : element is optional; must appear 0 or more time
  +          : element is mandatory; must appear 1 or more times
  <none>     : element is mandatory; must appear once and only once
-->

<!-- ============================================================= -->
<!ELEMENT node-extension (title, (leaf | node-extension)+)>
<!ATTLIST node-extension
        ID ID #IMPLIED
        xml:lang CDATA #IMPLIED
>
<!-- ============================================================= -->
<!ENTITY % show-list " (new | replace | embed | other | none) ">
<!ENTITY % actuate-list " (onLoad | onRequest | other | none) ">
<!ENTITY % operation-list " (new | append | replace | delete) ">
<!ENTITY % leaf-element " (title, link-text?) ">
<!ENTITY % leaf-att '
 ID              ID              #REQUIRED
 application-version CDATA          #IMPLIED
 version         CDATA           #IMPLIED
 font-library    CDATA           #IMPLIED
 operation       %operation-list;  #REQUIRED
 modified-file   CDATA           #IMPLIED
 checksum        CDATA           #REQUIRED
 checksum-type   CDATA           #REQUIRED
 keywords        CDATA           #IMPLIED
 xmlns:xlink     CDATA           #FIXED    "http://www.w3c.org/1999/xlink"
 xlink:type      CDATA           #FIXED    "simple"
 xlink:role      CDATA           #IMPLIED
 xlink:href      CDATA           #IMPLIED
 xlink:show      %show-list;     #IMPLIED
 xlink:actuate   %actuate-list;  #IMPLIED
 xml:lang        CDATA           #IMPLIED
 '>
<!ELEMENT leaf %leaf-element;>
<!ATTLIST leaf
        %leaf-att;
>
<!ELEMENT title (#PCDATA)>
<!ELEMENT link-text (#PCDATA | xref)*>

<!ELEMENT xref EMPTY>
<!ATTLIST xref
        ID ID #REQUIRED
        xmlns:xlink CDATA #FIXED "http://www.w3c.org/1999/xlink"
        xlink:type CDATA #FIXED "simple"
```

```
        xlink:role CDATA #IMPLIED
        xlink:title CDATA #REQUIRED
        xlink:href CDATA #REQUIRED
        xlink:show %show-list; #IMPLIED
        xlink:actuate %actuate-list; #IMPLIED
>
<!-- +++ -->
```

za-regional.xsl:

```
<?xml version="1.0" encoding="iso-8859-1" standalone="no"?>

<!--
        MCC ZA Regional XSL
        Version: 2.0
        State: final
        Date: 18/09/2016
        Authors: EXTEDO
-->

<xsl:stylesheet version="2.0"
        xmlns:xsl="http://www.w3.org/1999/XSL/Transform"
        xmlns:mcc="http://www.mccza.com"
        xmlns:xlink="http://www.w3c.org/1999/xlink">

  <xsl:output method="html" encoding="UTF-8" indent="no"/>

  <xsl:template match="/">
    <html>
      <head>
        <title>MCC ZA Module 1 - DTD version <xsl:value-of select="/mcc:za-backbone/@dtd-version"/></title>
        <style type="text/css">
                        h1, h2, h3, h4 {margin-top:3pt ; margin-bottom:0pt}
                        ul {margin-bottom:0pt ; margin-top:0pt}
                </style>
      </head>
                <body>
                        <center>
                                <h1>MCC ZA Module 1</h1>
                                <small>DTD version <xsl:value-of select="/mcc:za-backbone/@dtd-version"/></small>
                        </center>
                        <xsl:apply-templates select="//za-envelope"/>
                        <br/>
                        <xsl:apply-templates select="//m1-za"/>
                </body>
        </html>
        </xsl:template>
```

```
<xsl:template match="*|@*" mode="data">
	<xsl:value-of select="."/>
</xsl:template>

<xsl:template match="*|@*" mode="csv">
	<xsl:value-of select="."/>
	<xsl:if test="position() != last()"><xsl:text>, </xsl:text></xsl:if>
</xsl:template>

<xsl:template match="*|@*" mode="submission">
	<xsl:choose>
		<xsl:when test="@type='na-nce-ph'">New Application - New Chemical Entity - Pharmaceutical</xsl:when>
		<xsl:when test="@type='na-nce-b'">New Application - New Chemical Entity - Biological</xsl:when>
		<xsl:when test="@type='na-ms'">New Application - Multisource</xsl:when>
		<xsl:when test="@type='na-bs'">New Application - Biosimilar</xsl:when>
		<xsl:when test="@type='na-le'">New Application - Line Extension</xsl:when>
		<xsl:when test="@type='na-cu'">New Application - Call-up</xsl:when>
		<xsl:when test="@type='na-cm'">New Application - Complementary Medicines</xsl:when>
		<xsl:when test="@type='pre-reg-pa'">Response to Pre-reg Recommendation - Pharmaceutical and Analytical</xsl:when>
		<xsl:when test="@type='pre-reg-cl'">Response to Pre-reg Recommendation - Clinical</xsl:when>
		<xsl:when test="@type='pre-reg-pn'">Response to Pre-reg Recommendation - Proprietary Name</xsl:when>
		<xsl:when test="@type='pre-reg-sch'">Response to Pre-reg Recommendation - Scheduling</xsl:when>
		<xsl:when test="@type='pre-reg-insp'">Response to Pre-reg Recommendation - Inspectorate</xsl:when>
		<xsl:when test="@type='pre-reg-biol'">Response to Pre-reg Recommendation - Biological committee response</xsl:when>
		<xsl:when test="@type='pre-reg-cm'">Response to Pre-reg Recommendation - Complementary Medicines</xsl:when>
		<xsl:when test="@type='pre-reg-cr'">Response to Pre-reg Recommendation - Response to Council resolutions</xsl:when>
		<xsl:when test="@type='post-reg-insp'">Post-registration - Inspectorate</xsl:when>
		<xsl:when test="@type='post-reg-pa'">Post-registration - Pharmaceutical and Analytical</xsl:when>
		<xsl:when test="@type='post-reg-cl'">Post-registration - Clinical</xsl:when>
		<xsl:when test="@type='post-reg-pn'">Post-registration - Proprietary Name change application</xsl:when>
		<xsl:when test="@type='post-reg-pn-update'">Post-registration - Updates following a proprietary name change approval</xsl:when>
		<xsl:when test="@type='post-reg-hcr'">Post-registration - Applicant transfer, name and address change of applicant</xsl:when>
		<xsl:when test="@type='post-reg-biol'">Post-registration - Biologicals and biosimilars</xsl:when>
		<xsl:when test="@type='post-reg-cm'">Post-registration - Complementary Medicines</xsl:when>
		<xsl:when test="@type='resp-post-reg-insp'">Response to Post-registration - Inspectorate</xsl:when>
		<xsl:when test="@type='resp-post-reg-pa'">Response to Post-registration - Pharmaceutical and Analytical</xsl:when>
		<xsl:when test="@type='resp-post-reg-cl'">Response to Post-registration - Clinical</xsl:when>
		<xsl:when test="@type='resp-post-reg-pn'">Response to Post-registration - Proprietary Name change application</xsl:when>
```

```
                <xsl:when test="@type='resp-post-reg-pn-update'">Response to Post-registration - Updates following a proprietary name change approval</xsl:when>
                <xsl:when test="@type='resp-post-reg-hcr'">Response to Post-registration - Applicant transfer, name and address change of applicant</xsl:when>
                <xsl:when test="@type='resp-post-reg-biol'">Response to Post-registration - Biologicals and biosimilars</xsl:when>
                <xsl:when test="@type='resp-post-reg-cm'">Response to Post-registration - Complementary Medicines</xsl:when>
                <xsl:when test="@type='withdrawal'">Withdrawal of a Submission</xsl:when>
                <xsl:when test="@type='cancellation'">Cancellation of a Registered Product</xsl:when>
                <xsl:when test="@type='baseline'">Reformatting from Paper to eCTD</xsl:when>
            </xsl:choose>
        </xsl:template>


        <xsl:template match="*|@*" mode="efficacy">
            <xsl:choose>
                <xsl:when test="@data-type='non-cl'">Non-clinical</xsl:when>
                <xsl:when test="@data-type='cl'">Clinical</xsl:when>
                <xsl:when test="@data-type='be'">Bioequivalence Study</xsl:when>
                <xsl:when test="@data-type='other'">Other<xsl:text>: </xsl:text>
                    <xsl:if test="@description">
                        <xsl:value-of select="@description"/>
                    </xsl:if>
                </xsl:when>
                <xsl:when test="@data-type='na'">Not applicable</xsl:when>
                <xsl:otherwise>???</xsl:otherwise>
            </xsl:choose>
            <xsl:if test="position() != last()"><xsl:text>, </xsl:text></xsl:if>
        </xsl:template>

        <xsl:template match="*|@*" mode="multiapp">
            <tr>
                <td>
                    <xsl:value-of select="@proprietary-names"/>
                </td>
                <td>
                    <xsl:text> / </xsl:text>
                </td>
                <td>
                    <xsl:value-of select="@date-of-applications"/>
                </td>
```

```
            </tr>
    </xsl:template>

    <xsl:template match="za-envelope">
            <center>
                    <table width="90%" border="1px" frame="border" rules="groups" cellpadding="2" cellspacing="0">
                            <tr>
                                    <td colspan="2"><h3>Envelope</h3></td>
                            </tr>
                            <tr>
                                    <td width="25%">Application Number: </td>
                                    <td><xsl:apply-templates select="application-number" mode="csv"/></td>
                            </tr>
                            <tr>
                                    <td>Applicant: </td>
                                    <td><xsl:apply-templates select="applicant" mode="data"/></td>
                            </tr>
                            <tr>
                                    <td>Submission: </td>
                                    <td><xsl:apply-templates select="submission" mode="submission"/></td>
                            </tr>
                            <tr>
                                    <td>Proof of Efficacy: </td>
                                    <td><xsl:apply-templates select="submission/efficacy" mode="efficacy"/></td>
                            </tr>
                            <tr>
                                    <td>Proprietary Name: </td>
                                    <td><xsl:apply-templates select="proprietary-name" mode="csv"/></td>
                            </tr>
                            <tr>
                                    <td>Dosage Form: </td>
                                    <td>
                                            <xsl:apply-templates select="dosage-form" mode="csv"/>
                                    </td>
                            </tr>
                            <tr>
                                    <td>INN: </td>
                                    <td><xsl:apply-templates select="inn" mode="csv"/></td>
                            </tr>
                            <tr>
```

```
                        <td>eCTD Sequence: </td>
                        <td><xsl:apply-templates select="ectd-sequence" mode="data"/></td>
                    </tr>
                    <tr>
                        <td>Related eCTD Sequence: </td>
                        <td><xsl:apply-templates select="related-ectd-sequence" mode="csv"/></td>
                    </tr>
                    <tr>
                        <td>
                            Duplicate Applications:<br/>
                            <small>(Proprietary Names / Dates of Application)</small>
                        </td>
                        <td>
                            <table>
                                <xsl:apply-templates select="multiple-applications" mode="multiapp"/>
                            </table>
                        </td>
                    </tr>
                </table>
            </center>
        </xsl:template>

        <xsl:template match="leaf" mode="plain">
            <a>
                <xsl:attribute name="href"><xsl:value-of select="@xlink:href"/></xsl:attribute>
                <xsl:value-of select="title"/>
            </a>
            <xsl:text> </xsl:text>
            (<font color="red"><xsl:value-of select="@operation"/></font> - <font color="green"><xsl:value-of select="../@xml:lang"/></font>)
            <xsl:if test="position() != last()"><br/></xsl:if>
        </xsl:template>

        <xsl:template match="leaf">
            <li>
                <a>
                    <xsl:attribute name="href"><xsl:value-of select="@xlink:href"/></xsl:attribute>
                    <xsl:value-of select="title"/>
                </a>
                <xsl:text> </xsl:text>
                (<font color="red"><xsl:value-of select="@operation"/></font>)
```

```
                <xsl:if test="position() != last()"><br/></xsl:if>
        </li>
</xsl:template>

<xsl:template match="node-extension">
        <li><xsl:apply-templates select="title" mode="data"/>
                <ul type="square">
                        <xsl:apply-templates select="leaf | node-extension"/>
                </ul>
        </li>
</xsl:template>

<xsl:template match="m1-za">
        <center>
                <table width="90%" cellpadding="5" cellspacing="2">
                        <tr>
                                <td colspan="2"><h2>Module 1</h2></td>
                        </tr>
                        <tr>
                                <td width="5%" valign="top"><h3>1.0</h3></td>
                                <td width="95%">
                                        <h3>Letter of Application</h3>
                                        <xsl:apply-templates select="m1-0-application-letter"/>
                                </td>
                        </tr>
                        <tr>
                                <td valign="top"><h3>1.2</h3></td>
                                <td>
                                        <h3>Application</h3>
                                </td>
                        </tr>
                        <tr>
                                <td valign="top">
                                        <h4>1.2.1</h4>
                                </td>
                                <td>
                                        <h4>Application Form</h4>
                                        <xsl:apply-templates select="m1-2-application/m1-2-1-application-form"/>
                                </td>
                        </tr>
```

```
<tr>
    <td valign="top">
        <h4>1.2.2</h4>
    </td>
    <td>
        <h4>Annexes</h4>
    </td>
</tr>
<tr>
    <td valign="top">
        <h5>1.2.2.1</h5>
    </td>
    <td>
        <h5>Proof of Payment</h5>
        <xsl:apply-templates select="m1-2-application/m1-2-2-annexes/m1-2-2-1-proof-of-payment"/>
    </td>
</tr>
<tr>
    <td valign="top">
        <h5>1.2.2.2</h5>
    </td>
    <td>
        <h5>Letter of Authorisation</h5>
        <xsl:apply-templates select="m1-2-application/m1-2-2-annexes/m1-2-2-2-letter-of-authorisation"/>
    </td>
</tr>
<tr>
    <td valign="top">
        <h5>1.2.2.3</h5>
    </td>
    <td>
        <h5>Dossier Product Batch Information</h5>
        <xsl:apply-templates select="m1-2-application/m1-2-2-annexes/m1-2-2-3-dossier-product-batch-
information"/>
    </td>
</tr>
<tr>
    <td valign="top">
        <h5>1.2.2.4</h5>
    </td>
```

```
                <td>
                    <h5>Electronic Copy Declaration</h5>
                    <xsl:apply-templates select="m1-2-application/m1-2-2-annexes/m1-2-2-4-electronic-copy-declaration"/>
                </td>
            </tr>
            <tr>
                <td valign="top">
                    <h5>1.2.2.5</h5>
                </td>
                <td>
                    <h5>Curriculum Vitae of the Person Responsible for Pharmacovigilance</h5>
                    <xsl:apply-templates select="m1-2-application/m1-2-2-annexes/m1-2-2-5-cv-pharmacovigilance"/>
                </td>
            </tr>
            <tr>
                <td valign="top">
                    <h5>1.2.2.6</h5>
                </td>
                <td>
                    <h5>API Change Control</h5>
                    <xsl:apply-templates select="m1-2-application/m1-2-2-annexes/m1-2-2-6-api-change-control"/>
                </td>
            </tr>
            <tr>
                <td valign="top">
                    <h5>1.2.2.7</h5>
                </td>
                <td>
                    <h5>EMA Certificate for a Vaccine Antigen Master File (VAMF)</h5>
                    <xsl:apply-templates select="m1-2-application/m1-2-2-annexes/m1-2-2-7-vamf-certificate"/>
                </td>
            </tr>
            <tr>
                <td valign="top">
                    <h5>1.2.2.8</h5>
                </td>
                <td>
                    <h5>EMA Certificate for a Plasma Master File (PMF)</h5>
                    <xsl:apply-templates select="m1-2-application/m1-2-2-annexes/m1-2-2-8-pmf-certificate"/>
                </td>
```

```
</tr>
<tr>
	<td valign="top"><h3>1.3</h3></td>
	<td>
		<h3>South African Labelling and Packaging</h3>
	</td>
</tr>
<tr>
	<td valign="top">
		<h4>1.3.1</h4>
	</td>
	<td>
		<h4>South African Package Insert</h4>
	</td>
</tr>
<tr>
	<td valign="top">
		<h5>1.3.1.1</h5>
	</td>
	<td>
		<h5>Package Insert</h5>
		<xsl:apply-templates select="m1-3-za-labelling-packaging/m1-3-1-sapi/m1-3-1-1-pi"/>
	</td>
</tr>
<tr>
	<td valign="top">
		<h5>1.3.1.2</h5>
	</td>
	<td>
		<h5>Standard References</h5>
		<xsl:apply-templates select="m1-3-za-labelling-packaging/m1-3-1-sapi/m1-3-1-2-stdrefs"/>
	</td>
</tr>
<tr>
	<td valign="top">
		<h4>1.3.2</h4>
	</td>
	<td>
		<h4>Patient Information Leaflet</h4>
		<xsl:apply-templates select="m1-3-za-labelling-packaging/m1-3-2-pil"/>
```

```
            </td>
        </tr>
        <tr>
            <td valign="top">
                <h4>1.3.3</h4>
            </td>
            <td>
                <h4>Labels</h4>
                <xsl:apply-templates select="m1-3-za-labelling-packaging/m1-3-3-labels"/>
            </td>
        </tr>
        <tr>
            <td valign="top">
                <h4>1.3.4</h4>
            </td>
            <td>
                <h4>Braille</h4>
                <xsl:apply-templates select="m1-3-za-labelling-packaging/m1-3-4-braille"/>
            </td>
        </tr>
        <tr>
            <td valign="top"><h3>1.4</h3></td>
            <td>
                <h3>Information about the Experts</h3>
            </td>
        </tr>
        <tr>
            <td valign="top"><h4>1.4.1</h4></td>
            <td>
                <h4>Quality</h4>
                <xsl:apply-templates select="m1-4-expert-information/m1-4-1-quality"/>
            </td>
        </tr>
        <tr>
            <td valign="top"><h4>1.4.2</h4></td>
            <td>
                <h4>Non-Clinical</h4>
                <xsl:apply-templates select="m1-4-expert-information/m1-4-2-non-clinical"/>
            </td>
        </tr>
```

```
<tr>
	<td valign="top"><h4>1.4.3</h4></td>
	<td>
		<h4>Clinical</h4>
		<xsl:apply-templates select="m1-4-expert-information/m1-4-3-clinical"/>
	</td>
</tr>

<tr>
	<td valign="top"><h3>1.5</h3></td>
	<td>
		<h3>Specific Requirements for Different Types of Applications</h3>
	</td>
</tr>
<tr>
	<td valign="top"><h4>1.5.1</h4></td>
	<td>
		<h4>Literature Based Submissions</h4>
		<xsl:apply-templates select="m1-5-specific-requirements/m1-5-1-literature-based"/>
	</td>
</tr>
<tr>
	<td valign="top"><h4>1.5.2</h4></td>
	<td>
		<h4>Amendments/Variations</h4>
	</td>
</tr>
<tr>
	<td valign="top">
		<h5>1.5.2.1</h5>
	</td>
	<td>
		<h5>Tabulated Schedule of Amendments</h5>
		<xsl:apply-templates select="m1-5-specific-requirements/m1-5-2-amendment/m1-5-2-1-amendment-
schedule"/>
	</td>
</tr>
<tr>
	<td valign="top">
		<h5>1.5.2.2</h5>
```

```
                </td>
                <td>
                        <h5>Medicines Register Details</h5>
                        <xsl:apply-templates select="m1-5-specific-requirements/m1-5-2-amendment/m1-5-2-2-medicine-register"/>
                </td>
        </tr>
        <tr>
                <td valign="top">
                        <h5>1.5.2.3</h5>
                </td>
                <td>
                        <h5>Affidavit by Responsible Pharmacist</h5>
                        <xsl:apply-templates select="m1-5-specific-requirements/m1-5-2-amendment/m1-5-2-3-affidavit"/>
                </td>
        </tr>
        <tr>
                <td valign="top">
                        <h4>1.5.3</h4>
                </td>
                <td>
                        <h4>Proprietary Name Applications and Changes</h4>
                        <xsl:apply-templates select="m1-5-specific-requirements/m1-5-3-proprietary-name"/>
                </td>
        </tr>
        <tr>
                <td valign="top">
                        <h4>1.5.4</h4>
                </td>
                <td>
                        <h4>Genetically Modified Organisms</h4>
                        <xsl:apply-templates select="m1-5-specific-requirements/m1-5-4-gmo"/>
                </td>
        </tr>
        <tr>
                <td valign="top">
                        <h4>1.5.5</h4>
                </td>
                <td>
                        <h4>PI and PIL Amendments/Updates</h4>
                        <xsl:apply-templates select="m1-5-specific-requirements/m1-5-5-pi-amendment"/>
```

```
            </td>
        </tr>
        <tr>
            <td valign="top"><h3>1.6</h3></td>
            <td>
                <h3>Environmental Risk Assessment</h3>
            </td>
        </tr>
        <tr>
            <td valign="top"><h4>1.6.1</h4></td>
            <td>
                <h4>Non-GMO (Genetically Modified Organisms)</h4>
                <xsl:apply-templates select="m1-6-environ-risk-assessment/m1-6-1-nongmo"/>
            </td>
        </tr>
        <tr>
            <td valign="top">
                <h4>1.6.2</h4>
            </td>
            <td>
                <h4>GMO (Genetically Modified Organisms)</h4>
                <xsl:apply-templates select="m1-6-environ-risk-assessment/m1-6-2-gmo"/>
            </td>
        </tr>
        <tr>
            <td valign="top"><h3>1.7</h3></td>
            <td>
                <h3>Good Manufacturing Practice (GMP)</h3>
            </td>
        </tr>
        <tr>
            <td valign="top"><h4>1.7.1</h4></td>
            <td>
                <h4>Date of Last Inspection of Each Site</h4>
                <xsl:apply-templates select="m1-7-gmp/m1-7-1-last-inspection"/>
            </td>
        </tr>
        <tr>
            <td valign="top"><h4>1.7.2</h4></td>
            <td>
```

```
                <h4>Inspection Reports or Equivalent Document</h4>
                <xsl:apply-templates select="m1-7-gmp/m1-7-2-inspection-report-or-equivalent"/>
            </td>
        </tr>
        <tr>
            <td valign="top"><h4>1.7.3</h4></td>
            <td>
                <h4>Latest GMP certificate or a copy of the appropriate licence</h4>
                <xsl:apply-templates select="m1-7-gmp/m1-7-3-gmp-certificate"/>
            </td>
        </tr>
        <tr>
            <td valign="top"><h4>1.7.4</h4></td>
            <td>
                <h4>Release</h4>
            </td>
        </tr>
        <tr>
            <td valign="top">
                <h5>1.7.4.1</h5>
            </td>
            <td>
                <h5>API</h5>
                <xsl:apply-templates select="m1-7-gmp/m1-7-4-release/m1-7-4-1-api"/>
            </td>
        </tr>
        <tr>
            <td valign="top">
                <h5>1.7.4.2</h5>
            </td>
            <td>
                <h5>IPIs</h5>
                <xsl:apply-templates select="m1-7-gmp/m1-7-4-release/m1-7-4-2-ipi"/>
            </td>
        </tr>
        <tr>
            <td valign="top">
                <h5>1.7.4.3</h5>
            </td>
            <td>
```

```
                <h5>Finished Product Release Control (FPRC) Tests</h5>
                <xsl:apply-templates select="m1-7-gmp/m1-7-4-release/m1-7-4-3-fprc-tests"/>
            </td>
        </tr>
        <tr>
            <td valign="top">
                <h5>1.7.4.4</h5>
            </td>
            <td>
                <h5>Finished Product Release Responsibility (FPRR) Criteria</h5>
                <xsl:apply-templates select="m1-7-gmp/m1-7-4-release/m1-7-4-4-fprr-criteria"/>
            </td>
        </tr>
        <tr>
            <td valign="top"><h4>1.7.5</h4></td>
            <td>
                <h4>Confirmation of Contract</h4>
                <xsl:apply-templates select="m1-7-gmp/m1-7-5-contract-confirmation"/>
            </td>
        </tr>
        <tr>
            <td valign="top"><h4>1.7.6</h4></td>
            <td>
                <h4>CPP (WHO Certification Scheme)</h4>
                <xsl:apply-templates select="m1-7-gmp/m1-7-6-cpp"/>
            </td>
        </tr>
        <tr>
            <td valign="top">
                <h4>1.7.7</h4>
            </td>
            <td>
                <h4>SAPC Registration</h4>
                <xsl:apply-templates select="m1-7-gmp/m1-7-7-sapc-reg"/>
            </td>
        </tr>
        <tr>
            <td valign="top"><h4>1.7.8</h4></td>
            <td>
                <h4>Registration with Registrar of Companies</h4>
```

```
                    <xsl:apply-templates select="m1-7-gmp/m1-7-8-comp-reg"/>
                </td>
            </tr>
            <tr>
                <td valign="top"><h4>1.7.9</h4></td>
                <td>
                    <h4>Other Documents Relating to the Applicant/PHCR</h4>
                    <xsl:apply-templates select="m1-7-gmp/m1-7-9-docs-phcr"/>
                </td>
            </tr>
            <tr>
                <td valign="top"><h4>1.7.10</h4></td>
                <td>
                    <h4>Sample and Documents</h4>
                </td>
            </tr>
            <tr>
                <td valign="top">
                    <h5>1.7.10.1</h5>
                </td>
                <td>
                    <h5>Confirmation of Submission of Sample</h5>
                    <xsl:apply-templates select="m1-7-gmp/m1-7-10-sample-documents/m1-7-10-1-sample-submission-
confirmation"/>
                </td>
            </tr>
            <tr>
                <td valign="top">
                    <h5>1.7.10.2</h5>
                </td>
                <td>
                    <h5>Batch Manufacturing Record of the Sample</h5>
                    <xsl:apply-templates select="m1-7-gmp/m1-7-10-sample-documents/m1-7-10-2-sample-bmr"/>
                </td>
            </tr>
            <tr>
                <td valign="top">
                    <h5>1.7.10.3</h5>
                </td>
                <td>
```

```
                    <h5>CoA of the Sample</h5>
                    <xsl:apply-templates select="m1-7-gmp/m1-7-10-sample-documents/m1-7-10-3-sample-coa"/>
                </td>
            </tr>
            <tr>
                <td valign="top">
                    <h4>1.7.11</h4>
                </td>
                <td>
                    <h4>Certified Copy of a Permit to Manufacture Specified Schedule 5, Schedules 6, 7 and 8 Substances</h4>
                    <xsl:apply-templates select="m1-7-gmp/m1-7-11-manufacturing-permit"/>
                </td>
            </tr>
            <tr>
                <td valign="top">
                    <h4>1.7.12</h4>
                </td>
                <td>
                    <h4>Inspection Flow Diagram</h4>
                    <xsl:apply-templates select="m1-7-gmp/m1-7-12-inspection-flow-diagram"/>
                </td>
            </tr>
            <tr>
                <td valign="top">
                    <h4>1.7.13</h4>
                </td>
                <td>
                    <h4>Organogram</h4>
                    <xsl:apply-templates select="m1-7-gmp/m1-7-13-organogram"/>
                </td>
            </tr>
            <tr>
                <td valign="top"><h3>1.8</h3></td>
                <td>
                    <h3>Details of compliance with screening outcomes</h3>
                    <xsl:apply-templates select="m1-8-compliance-screening"/>
                </td>
            </tr>
            <tr>
```

```
                <td valign="top">
                        <h3>1.9</h3>
                </td>
                <td>
                        <h3>Individual Patient Data - Statement of Availability</h3>
                        <xsl:apply-templates select="m1-9-indiv-patient-data"/>
                </td>
        </tr>
        <tr>
                <td valign="top">
                        <h3>1.10</h3>
                </td>
                <td>
                        <h3>Foreign Regulatory Status</h3>
                </td>
        </tr>
        <tr>
                <td valign="top"><h4>1.10.1</h4></td>
                <td>
                        <h4>List of countries in which an application for the same product as being applied for has been submitted</h4>
                        <xsl:apply-templates select="m1-10-foreign-reg-status/m1-10-1-countries-same-appl"/>
                </td>
        </tr>
        <tr>
                <td valign="top"><h4>1.10.2</h4></td>
                <td>
                        <h4>Registration Certificate or Marketing Authorisation</h4>
                        <xsl:apply-templates select="m1-10-foreign-reg-status/m1-10-2-foreign-reg-certif-or-ma"/>
                </td>
        </tr>
        <tr>
                <td valign="top">
                        <h4>1.10.3</h4>
                </td>
                <td>
                        <h4>Foreign Prescribing and Patient Information</h4>
                        <xsl:apply-templates select="m1-10-foreign-reg-status/m1-10-3-foreign-pi"/>
                </td>
        </tr>
```

```
                        <tr>
                            <td valign="top">
                                <h4>1.10.4</h4>
                            </td>
                            <td>
                                <h4>Data Set Similarities</h4>
                                <xsl:apply-templates select="m1-10-foreign-reg-status/m1-10-4-data-set-similarities"/>
                            </td>
                        </tr>
                        <tr>
                            <td valign="top"><h3>1.11</h3></td>
                            <td>
                                <h3>Bioequivalence Trial Information</h3>
                                <xsl:apply-templates select="m1-11-be-trial-info"/>
                            </td>
                        </tr>
                        <tr>
                            <td valign="top">
                                <h3>1.12</h3>
                            </td>
                            <td>
                                <h3>Paediatric Development Programme</h3>
                                <xsl:apply-templates select="m1-12-paediatric-dev-program"/>
                            </td>
                        </tr>
                        <tr>
                            <td valign="top">
                                <h3>1.13</h3>
                            </td>
                            <td>
                                <h3>Risk Management Plan</h3>
                                <xsl:apply-templates select="m1-13-risk-management-plan"/>
                            </td>
                        </tr>
                    </table>
                </center>
            </xsl:template>

</xsl:stylesheet>
```